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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

KAUFFMAN
X Skating
Scott.

The Honourable Mr. Justice S.G.M. Grange

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Transcript of evidence
for

December 1, 1983

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1 ROYAL COMMISSION OF INQUIRY INTO CERTAIN
2 DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

3 Hearing held on the 8th Floor,
4 180 Dundas Street West, Toronto,
5 Ontario, on Thursday, the 1st
day of December, 1983.

6

7 THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
8 THOMAS MILLAR - Administrator
9 MURRAY R. ELLIOT - Registrar

10 - - - - -

11 APPEARANCES:

12 P.S.A. LAMEK, Q.C.) Commission Counsel
13 E. CRONK)
14 D. HUNT) Counsel for the Attorney
15 L. CECCHETTO) General and Solicitor General
of Ontario (Crown Attorneys
and Coroner's Office)
16 I.G. SCOTT, Q.C.) Counsel for The Hospital for
17 M. THOMSON) Sick Children
R. BATTY)
18 D. YOUNG Counsel for The Metropolitan
19 Toronto Police
20 W.N. ORTVED Counsel for numerous Doctors
21 at The Hospital for Sick
22 Children
23 B. SYMES Counsel for the Registered
24 Nurses' Association of Ontario
25 and 35 Registered Nurses at
The Hospital for Sick Children

(Cont'd)



1 APPEARANCES (Continued):

2 D. BROWN Counsel for Susan Nelles -
3 Nurse

4 G.R. STRATHY) Counsel for Phyllis Trayner -
5 E. FORSTER) Nurse

6 J.A. OLAH Counsel for Janel Brownless -
7 R.N.A.

8 B. JACKMAN Counsel for Mrs. M. Christie -
9 R.N.A.

10 S. LABOW Counsel for Mr. & Mrs. Gosselin,
11 Mr. & Mrs. Gionas, Mr. & Mrs.
12 Inwood, Mr. & Mrs. Turner, Mr.
13 Mrs. Lutes, and Mr. & Mrs.
14 Murphy (parents of deceased
15 children)

16 F.J. SHANAHAN Counsel for Mr. & Mrs. Dominic
17 Lombardo (parents of deceased
child Stephanie Lombardo); and
Heather Dawson (mother of
deceased child Amber Dawson)

18 W.W. TOBIAS Counsel for Mr. & Mrs. Hines
(parents of deceased child
Jordan Hines)

19 J. SHINEHOFT Counsel for Lorie Pacsai and
20 Kevin Garnet (parents of deceased
child Kevin Pacsai).



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I N D E X O F W I T N E S S E S

2

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Cross-Examination by Mr. Strathy

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Cross-Examination by Mr. Scott

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I N D E X O F E X H I B I T S

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NO.

Description

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13

275

Copy of Dr. Kauffman's handwritten notes re Rating No. 1. 5988

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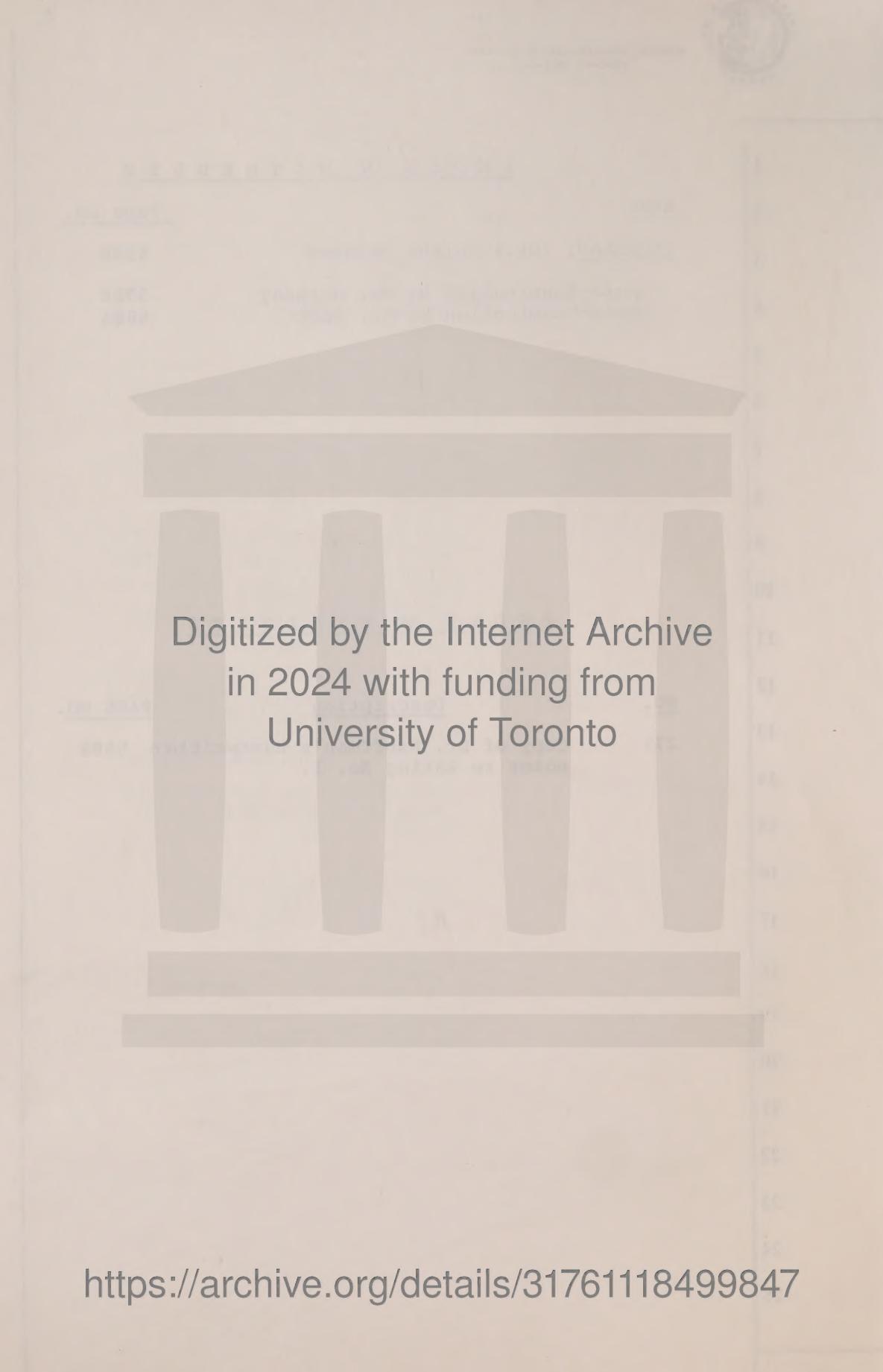
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1 ---On commencing at 9:30 a.m.

2 THE COMMISSIONER: Miss Cronk?

3 MS. CRONK: Good morning, sir.

4 I now have a typewritten version of the breakdown
5 of Dr. Kauffman's probability rating No. 1 scores,
6 his handwritten notes.

7 THE COMMISSIONER: What will we call
8 this? "A breakdown of Rating No. 1".

9 MS. CRONK: Thank you, sir.

10 THE COMMISSIONER: No. 275.

11 ---EXHIBIT NO. 275: Copy of Dr. Kauffman's hand-
12 written notes re Rating No. 1.

13 THE COMMISSIONER: Yes, Mr. Strathy.

14 MR. OLAH: Excuse me, sir, what is
15 the number?

16 THE COMMISSIONER: Exhibit 275.

17 DR. RALPH KAUFFMAN, Resumed

18 CROSS-EXAMINATION BY MR. STRATHY:

19 Q. Doctor, just before we begin
20 you mentioned yesterday I believe that you had at
21 the request of the Crown Attorneys reviewed the
22 charts of the children that are under consideration;
23 some 30 odd charts.

24 Do I understand you to say that that
25 process took approximately a day?

26 A. It was approximately a day,



1

2

yes.

3

4

Q. So it was done in the course
of one particular day?

5

A. Yes.

6

7

Q. And that was the only
opportunity you had to review these charts?

8

A. The complete chart, yes.

9

Q. And are we talking about 30
or 35 charts?

10

A. 37.

11

Q. 37.

12

A. To my recollection.

13

Q. Now, Doctor, I have read your
evidence at the Gary Murphy Inquest, and Miss Cronk
referred to it yesterday. I understood you to say
at that inquest as you have said in fact today and
it is clear in your report even though digoxin as
a drug has been around for many years there is still
a great deal that we do not know about it.

19

20

Is that a fair statement of your
belief?

21

A. I think I would agree with that,
yes.

22

Q. And that it is really only in
recent years that physicians and pharmacologists are

23

25



1

2 beginning to understand how the drug actually
3 operates in the body?

4 A. I think the knowledge has
5 expanded a great deal in recent years and there
6 is still a great deal to learn.

7 Q. Particularly I suppose with
8 the development of radioimmunoassay in the 1970s
9 your knowledge has expanded due to that fact?

10 A. That is correct. That was
11 a contributor.

12 Q. And is assisting physicians
13 and pharmacologists in their understanding of the
14 drug?

15 A. That is correct.

16 Q. But you have also expressed
17 a number of areas where it is clear that our
18 knowledge is at best incomplete. For example,
19 the distribution of the drug in the various tissues
20 of the body?

21 A. There is a lot of uncertainty
22 there and a lot that we don't know yet.

23 Q. And also clearly in the
24 measurement of digoxin in tissues and serum post
25 mortem?

26 A. I would agree with that.



1

2 Q. And indeed in the area
3 particularly of tissues and the half life of drug
4 in the tissues; again it is an area we don't know
5 too much about?

6

7 A. Just starting to get some
8 information on that very recently.

9

10 Q. And when we are talking about
11 post mortem life in tissue again as you have
12 explained that is another area where our knowledge
13 is just beginning to develop?

14

A. That is incomplete.

15

16 Q. Now, Doctor, dealing with
17 the symptoms of digoxin toxicity I take it you would
18 agree that the symptomatic signs of digoxin in
19 infants are non-specific?

20

21 A. I would agree with that in
22 general, yes.

23

24 Q. And indeed that there are
25 symptoms that can be due to other factors including
the clinical condition of the child?

1

A. They can in many cases, yes.

2

3 Q. So in a clinical condition
4 it may be difficult to know whether a specific
5 symptom is due to digoxin toxicity or not?

6

7 A. That is correct.

8

9



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2

Q. And I would like to put to you, Doctor, a statement of Dr. Hastreiter and I believe you met Dr. Hastreiter when you were working on the police team?

5

A. That is correct.

6

7

Q. And the statement comes from Dr. Hastreiter's report which is Exhibit 264, page number 27.

8

9 Dr. Hastreiter says this, and if you would listen to the quotation ---

10

11

A. I am sorry, which report are you referring to?

12

13

14

15

Q. Dr. Hastreiter has given us or his counsel has given us a big report of Dr. Hastreiter. Have you read this report or have you ever seen it before?

16

17

A. Is that the one you showed me - is that the case summaries?

18

19

Q. Case summaries, yes.

20

A. Yes, yes.

21

22

Q. Well, included in this volume, and you needn't dig it out I will try and read it slowly.

A. Okay.

23

24

Q. At page 27 Dr. Hastreiter was

25



1

2 answering certain questions put to him by Sergeant
3 Warr and he says this:

4 "In my opinion the only true proof
5 of digoxin toxicity is the demonstration
6 of high concentration of the drug in
7 blood or tissue. Digoxin intoxication
8 can mimic many other conditions and
9 particularly in infants who are
10 seriously and acutely ill from other
11 causes, the differential diagnosis can
12 be extremely difficult."

13 There are really two statements there,
14 but are you able to adopt that as a reflection of
15 your views?

16 A. There may be even more than
17 two statements there.

18 Q. Do you want me to break it
19 down?

20 A. I probably should look at
21 it because I don't know if I would agree with it
22 ~~in~~ toto as stated. I really don't know.

23 Q. All right. Let's break it
24 down.

25 MR. YOUNG: I think, Mr. Commissioner,
for other counsel and for the witness this is



1

2 Exhibit 264 I believe.

3 THE COMMISSIONER: Yes.

4 MR. STRATHY: I thought I said that.

5 MR. YOUNG: Oh, you may have, Mr.
Strathy.

6 THE COMMISSIONER: The only copy we
7 have here I have appropriated to myself.

8 MR. YOUNG: I have another copy if
9 that will assist.

10 MR. STRATHY: Well, I will read it out
11 loud slowly.

12 Q. So, Doctor, it starts:

13 "In my opinion the only true proof
14 of digoxin toxicity is a demonstration
15 of high concentration of the drug in
blood or tissue."

16 Now stopping there is that a statement that you
17 are prepared to adopt?

18 A. I am not willing to adopt
19 that statement as it is stated. I think that even
20 high concentrations in blood or serum, ignoring
21 tissue for the moment, may or may not indicate
digoxin toxicity.

22 Tissue, depending on what you mean
23 by "high concentration" possibly. The statement

24

25



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2 "true proof" I can't totally agree with because I
3 think that you can't prove digoxin toxicity with
4 any single piece of information. I think you have
5 to put the composite together of clinical symptoms
6 and signs, electrocardiographic evidence, possibly
7 clinical chemistry evidence and digoxin concentration
evidence.

8

Q. So ----

9

10 A. I think it is dangerous to
say that any one of those is the only true proof.

11

12 Q. So in and of itself then high
13 levels or high concentrations in blood, let us say,
may not necessarily be a sign of digoxin toxicity.

14

15 A. Depending on what you mean
16 by "high". It is very dependent on the time after
17 the dose is administered that you obtain the
concentration, the sample for the concentration
measurement as we pointed out.

18

19 Q. And I take it, Doctor, from
what you said as far as the first sentence is
20 concerned you would not go as far as Dr. Hastreiter
21 has perhaps on the face of it and you would suggest
22 that simply looking at a high concentration on its
own may not be enough to show digoxin toxicity?

23

24 A. Yes, I think that is the point

25



1

2 I am making.

3 Q. All right. I think you would
4 agree, however, with the second paragraph, the
5 second sentence?

6 A. Yes, I ---

7 Q. That:

8 "Digoxin intoxication can mimic many
9 other conditions and particularly in
10 infants who are seriously and acutely
11 ill from other causes, the differential
12 diagnosis can be extremely difficult."

13 A. Yes, I would agree with that.

14 Q. So that when we are looking
15 at a particular digoxin level and also looking at
16 symptoms in the child we have to be aware that those
17 symptoms can reflect other conditions including
18 the child's underlying disease?

19 A. Yes, that is correct.

20 Q. Doctor, we have heard that
21 there was a conference on digoxin here in Toronto
22 in the past month. Were you present at the
23 conference?

24 A. Yes, I participated in that
25 conference.

Q. And at that conference were



1

2 a number of the uncertainties about digoxin that
3 you referred to here today, were those discussed
4 at the conference?

5 A. Among the discussions, those
6 were certainly part of the discussion, yes.

7 Q. Now, Doctor, dealing again
8 with your evidence at the Murphy Inquest you
9 discussed this subject yesterday, and you pointed
10 out that your hypothesis No. 5 which you ultimately
11 felt was the most likely if I could put it no
12 higher than that; you indicated even with the
hypothesis No. 1 you had some difficulties?

13 A. I was uncomfortable with
14 it, yes, but it was the best of the things I could
15 think of to help shed some light on that situation.

16 Q. And what was it about
17 hypothesis No. 5 that made you uncomfortable?

18 A. Well, I think that among
19 the things that bothered me was that we didn't have
20 much information on the blood gas situation or the
21 electrolyte situation or the renal function
22 situation of Gary Murphy shortly before he died.

23

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2 It was clear from the chart that he
3 was progressively deteriorating and becoming rapidly
4 much sicker but there wasn't much information, as I
5 recall, right around the time of his death and shortly
6 before because people had made the decision that he
7 couldn't be cured, he couldn't be kept alive
8 indefinitely and that the most humane thing was to
9 keep him comfortable and love him and let him die
whenever that time came.

10 So, a lot of medical intervention was
11 not taking place. So, we had a ~~posit~~^{paucily} of concrete
12 information upon which to base a hypothesis, including
13 digoxin concentration.

14 The other thing that bothered me was
15 that my hypothesis was I thought a very theoretical
16 hypothesis and as I stated I think in my testimony
17 at that time, I really didn't have any hard objective
18 scientific evidence that indeed this kind of thing
19 could occur. I was basing it on indirect evidence
20 from a general knowledge of how digoxin distributed in
21 the body and my understanding of digoxin binding to
22 tissues and to specific receptors and what things
23 might possibly affect that binding.

24 Q. Well then, on that point,
25 Doctor, your fifth hypothesis, is it fair to



B.2

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2 characterize that as it has been characterized as an
3 abnormal pathophysiology?

4

5 A. I based it on the fact that
6 there was abnormal anatomical and - let me say it
7 this way. There were anatomical, severe anatomical
8 and physiological abnormalities in that patient
9 during his life and leading up to the time of his
hypothesis.

10

11 Q. I'm just trying to establish
a phrase that we can use in understanding ourselves.
12 Is that a fair description, abnormal physiology?

13

A. Right, I think so.

14

15 Q. You mentioned that in your
view it was a theoretical explanation for the death.
16 Had you, prior to your participation in the Gary Murphy
17 inquest in May of 1983, ever seen any references in
the literature to abnormal pathophysiology with
respect to digoxin?

18

19 A. I can't say at the moment that
I hadn't. I can't consciously think at this moment
20 of a specific reference. That is a commonly used
21 concept.

22

Q. In relation to drugs?

23

A. In relation to medicine in
24 general.

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Q. All right.

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A. And I can't say definitely

that I had never considered that concept in relation to digoxin prior to this. In fact, if I had not consciously thought about it previously I probably would not have arrived at that particular hypothesis.

Q. Well, let me put it this way.

Can you refer us today to any reported cases in the literature of abnormal pathophysiology with respect to digoxin?

A. As I stated at that time I wasn't aware of this kind of thing being documented previously.

Q. Well, perhaps if you do become aware of it being documented previously, even after you have given your evidence today or tomorrow you might refer it to Miss Cronk.

A. Okay.

Q. Doctor, with respect to this whole abnormal pathophysiology aspect of digoxin, I think you would probably agree that if it is an explanation for the Gary Murphy case it may well be another area where our knowledge about digoxin is fairly embrionic.

A. I think our knowledge is



B.4

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2 very minimal in that area in terms of concrete
3 information.

4 Q. Because surely if there is
5 something such as abnormal pathophysiology which
6 creates an effect such as you posited it may have in
7 Gary Murphy, it is entirely possible it may in other
8 circumstances create the same effect in other children?

9 A. It could under similar
circumstances.

10 Q. And the parameters of those
11 similar circumstances we really don't know?

12 A. No. We can, at least, I
13 limited those parameters based on the factors I thought
14 could do such a thing. But the experiments to my
15 knowledge have not been done.

16 Q. Doctor, at your digoxin
17 conference, or the digoxin conference in Toronto in
18 the past month, was this question of endogenous
19 digoxinlike substance discussed?

20 A. Yes, it was.

21 Q. Was Dr. Seccombe from Vancouver
22 present at that time?

23 A. No, I don't believe he was. The
24 individual who led the discussion on that was from
25 St. Louis.

(2) 24

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B.5

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Q. And did that focus upon the relatively recent discovery of an endogenous digoxin-like substance?

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A. I can't really comment on that because that was a separate workshop. I was chairing a different workshop, and, so, I couldn't attend that one and so I don't know what the - and I haven't seen a transcript of the workshop so, I can't really comment on what that discussion was. I am aware of the general topic but I don't know what the discussion was at that workshop.

12

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Q. Can you tell us when you first became aware of this endogenous digoxinlike substance or the theory that there was such a substance?

A. Some time during this past year.

Q. And was it prior to your participation on the police team?

A. It was subsequent to that.

Q. Was it subsequent to the preparation of your various reports, your individual case summaries?

A. Yes, that is correct, it was subsequent to the preparation of that report, including the January letter.

Q. I take it you yourself have



B.6

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2 not done any particular research in this field, any
3 research in that field?

4 A. That is correct.

5 Q. Now, is your knowledge of this
6 substance sufficient to let you know whether or not
7 it is something which appears in tissues?

8 A. I'm not aware of any information
9 right now that tells us whether or not this substance
10 is a problem in tissue assays.

11 Q. That's not to say there may
12 not be information to that effect.

13 A. I have seen no published
14 information about that or heard any papers presented
15 at meetings during the past year or two specifically
16 regarding that.

17 Q. Well, just to assist you, there
18 has been evidence before the Commission from
19 Dr. Seccombe. Do you know Dr. Seccombe?

20 A. I don't know him. I know who
21 he is from this work that he did but I don't know him.

22 Q. There has been evidence of
23 Dr. Seccombe before the Commission that this substance
24 X and, in fairness to you, he was a little discreet
25 about where his research is going for reasons which
I think you can understand. But he did suggest that



B.7

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2 their preliminary studies had suggested that Substance
3 X may in fact appear in tissues. I gather you are
4 not aware of that however?

5 A. No. I don't know either way,
6 really can't comment on it.

7 Q. Now, let us posit this
8 situation. If Substance X is in fact an endogenous
9 digoxinlike substance which is in effect manufactured
10 in the body and in fact will be manufactured in the
11 body even of people or children who are not receiving
12 digoxin and if in fact it does appear in the tissues,
13 that may explain in the particular case the presence
14 of something that looks like digoxin in post mortem
15 tissues of a particular infant?

16 A. If it was there in adequate
17 quantities and interacting with the antibody it could
18 I think.

19 Q. Thank you, Doctor. I want to
20 deal now with some of the specific children that you
21 have given evidence about.

22 Firstly, I want to ask you to refer
23 to the case of Jordan Hines.

24 A. Okay. Let me get a copy of
25 the chart, please.

Q. Can we have a copy of the chart,
26 please?



B.8

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THE COMMISSIONER: Yes. Perhaps

if you would let us know which ones you are going to do so the Registrar can get them.

5

6

MR. STRATHY: I don't know that we are going to need many of the charts but the Hines chart is Exhibit 103.

7

8

9

10

Just for your reference, Mr. Commissioner, and the witness, the children I propose to deal with are Hines, Cook, Belanger, Lombardo, Miller, Pacsai, Inwood.

11

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Q. Dealing with Hines, Doctor, you made reference to the digoxin levels in the child and those levels are found in Mr. Cimbura's report at page 6 and somewhat later in the report as well, but you are aware I think that all these levels in the case of Hines are levels from exhumed specimens?

16

A. Yes, that is correct.

17

18

19

MS. CRONK: I'm sorry, Mr. Strathy, but there are of course fixed tissue specimens against Jordan Hines.

20

21

THE WITNESS: I guess that is not correct. You say it is on page 6 of Mr. Cimbura's report?

22

23

MR. STRATHY: Q. Yes, that's right. Page 6 is the fixed tissue, excuse me.

24

25

No!
#1.

Shattock knows, from Grinbom's w.
that when a concentration is
reported as "digoxin" it means
the level was determined by
RIA - HPLC - RIA !



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C
DMra

2 A. I'm sorry, I have different
3 numbers.

4 Q. Well, we are talking about
5 different reports.

6 A. Oh, okay.

7 Q. Yes, you are right. Now
8 sample T60 tissue and fluid from the heart 118 nano-
9 grams per gram of digoxin and digoxinlike substances,
10 concentration of digoxin 52 nanograms per gram. Right
11 atrium 45 nanograms per gram of digoxin and digoxin-
12 like substances. Septum 174 nanograms per gram of
13 digoxin and digoxinlike substances, 89 nanograms per
14 gram of digoxin. And then tissue in jar, liver after
15 exhumation 240 nanograms per gram. Then in a later
16 report, doctor, and I don't know that you need to go
17 to it, there is reference to muscle from the right
18 thigh after exhumation 56 nanograms per gram.

19 A. And that included both digoxin
20 and digoxinlike substances?

21 Q. It says nanograms per gram of
22 digoxin, it doesn't, there is no information --

23 A. It doesn't make a differential?

24 Q. That is right. Then a subse-
25 quent report talks about heart reported to be a
mixture of tissue and Ely medium 9 nanograms per



1
C2 2 millilitre of digoxin. A subsequent one lung a mix-
3 ture of tissue and Ely medium 10 nanograms per milli-
4 litre of digoxin.

5 Now in all of these things where we
6 have a mixture of digoxin and digoxinlike substances,
7 we are seeing presumably under radioimmunoassay
8 breakdown products, or some of the breakdown products
9 of digoxin.

10 A. It was my understanding from
11 talking to Mr. Cimbura and looking at his laboratory
12 that what he did was run -- assay the samples with the
13 radioimmunoassay without doing any separation and then
14 ran the extract of the sample through high pressure
15 liquid chromatography and collected the appropriate
16 fraction and did the radioimmunoassay again on that
17 fraction, attempting to separate the true digoxin
18 from things that might bind to the antibody but were
19 not digoxin. My concept was at that time that these
20 could be comprised of either breakdown products of
21 digoxin which was originally there, or possibly
22 endogenous substances which will be separated from
23 true digoxin in the HPLC process.

24 Q. So that at least in the first
25 measurement before the HPLC when you measured the
substance you are getting some of these metabolites of



1

C3 2 digoxin.

3 A. Metabolites or other inter-
4 fering substances.

5 Q. But as I understand it with
6 HPLC you are only going to screen out those metabolites
7 or endogenous substances that you know about and which
8 you are able to take a sample on?

9 A. I am not sure that is totally
10 true. You should be able to separate digoxin itself
11 on the HPLC from other substances that do not co-
12 migrate with it on the column, and you may not be
13 aware of what all those other substances are.

14 Q. So if there are other sub-
15 stances that co-migrate with digoxin on the column
16 you are not aware of that, you may not in fact
17 separate them out with HPLC?

18 A. You may not and then it could be
19 subject to an error which would only occur if they
20 co-migrate on that particular HPLC system and also
21 interact to some degree with the antibody.

22 Q. And if we are positing an
23 endogenous digoxinlike substance that we as yet may
24 not know very much at all about, it is entirely
25 possible that that substance may be of the kind that
co-migrates on the column, and because you don't know



1
C4 2

that --

3 A. You can't run controls to see
4 if the separation is separating it.

5 Q. Precisely. Now, doctor, on
6 the subject of Hines, Baby Hines, I haven't gone
7 through your curriculum vitae in any detail, but I
8 don't recall that you have any training as a patholo-
9 gist, am I right in that?

10 A. No, I am not a pathologist.

11 Q. Nor do you have cardiology
12 training?

13 A. That is correct.

14 Q. In reviewing this particular
15 chart, may we take it that in view of the time
16 constraints placed on you you really did not have
17 more than half an hour to go through Baby Hines'
18 chart?

19 A. That is not totally true, because
20 I didn't divide my time equally with each chart and
21 there were some charts I spent several hours with.

22 Q. Do you have a recollection of
23 how long you spent with this chart?

24 A. No, I don't, no, but I'm sure
25 it is one of the ones I spent more time with.

Q. I was interested in your



1

C5 2 comment, doctor, that you didn't consider SIDS as a
3 reasonable possibility in the case of this child, am
4 I doing justice to you?

5 A. I think that is a fair summary
6 of my comments the other day.

7 Q. Well, I was interested in that
8 comment because you said that one of the factors that
9 influenced you in coming to that conclusion was that
10 there was nothing in the history of the child which
would point you to SIDS, do you recall saying that?

11 A. No, I don't think that is what
12 I said.

13 Q. What do you recall?

14 A. I think - and I would like to
15 look at my testimony. What I think I said was that
16 there were other factors in the history that led me
to believe it was not SIDS.

17 Q. My recollection was that it was
18 a broader statement than that.

19 A. I would have to refer to my
20 testimony.

21 Q. I don't think we need to go
22 into it in that detail.

23 A. There is a difference and that
24 is the only reason I disagreed with you just now.

25



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C6

2 Q. I want to refer you to the
3 history of the child, and in particular to page 28
4 of the chart, this is a summary of the history, do you
5 have that?

6 A. Yes, I do.

7 Q. It is in the preliminary autopsy
8 report, and it starts on the third line:

9 "The infant was well until one day
10 prior to admission, when he was found
11 by his mother in bed, grey-blue,
12 with shallow breathing. She picked
13 him up and shook him. The child then
14 choked and cried. There were a few
15 more episodes of shallow respirations
16 followed by slate grey-blue dis-
17 colouration. Each of these responded
18 to shaking. The baby had not been
19 active or feeding well for a few
20 days prior to this. There was no
21 fever. He was admitted to North
22 York General Hospital where he was
23 found to have spells of apnea,
24 associated with bradycardia followed
25 by tachycardia."

Now, doctor, just going back to that



1

C7 2 initial episode when:

3 "....the child was found by his
4 mother in bed grey-blue with shallow
5 breathing. She picked him up and
6 shook him. The child then choked
7 and cried..."

8 Is that in your view consistent with
9 a missed-SIDS episode?

10 A. It can be consistent with a
11 lot of things and that would be one of them. It could
12 be consistent, what I thought when I initially looked
13 at this chart was that this baby had sepsis and then
14 when the cultures were finally reported they were
15 negative. As I said the other day that doesn't totally
16 rule out sepsis but it makes it less likely. It could
17 also be due to an upper respiratory infection in a
18 baby this age. It could be due to an arrhythmia of
19 some sort. It could be due to a seizure. With this
 kind of information it could be due to a number of
 things.

20 Q. All right. Certainly one of
21 those things that we can point to would be a missed-
22 SIDS episode?

23 A. At that point with that kind of
24 information among the differential diagnoses I think

25



Kauffman
cr.ex. (Strathy)

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C8 2 SIDS is a reasonable one, yes.

3 Q. And then the subsequent
4 admissions at North York General Hospital when the
5 child was found to have spells of apnea, and would
6 that also be consistent with the missed-SIDS episode?

7 A. If that was the only thing
8 that was going on that could be consistent with a
baby who had had a close call with SIDS, yes.

9 Q. And as I understand it children
10 who have had one missed-SIDS are particularly sus-
11 ceptible to subsequent SIDS episodes?

12 A. Well, I think we get into a
13 grey area here. One thing I want to point out is
14 I think it is important to conceptually not make
15 apnea equivalent to SIDS or missed-SIDS. Apnea can
16 be caused in a baby this age by a large number of
17 pediologic factors. Whatever SIDS is can be
18 associated with apnea, or apnea can be a forerunner
19 of a baby that eventually dies from SIDS.

20 On the floor of the hospital where I
21 attend we see enormous numbers of babies admitted
22 with histories of apnea. We have one room that is
23 devoted totally to doing nothing but pneumograms on
24 babies who are suspected or known to have apnea, and
25 obviously most of those babies are not missed-SIDS.



1

C9 2 So I think it is important conceptually not to equate
3 the two.

4

5 Q. Yes. Doctor, the preliminary
6 autopsy is signed by Dr. Becker; do you know anything
7 about Dr. Becker or his qualifications?

8

9 A. I don't know. I know he is an
10 eminent pathologist I don't know him personally at all.

11

12 Q. Presumably you are not aware
13 that he has given presentations at various conferences
14 with respect to SIDS?

15

16 A. I am aware that he has done
17 a great deal of research on SIDS, I have never heard
18 any of his presentations.

19

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Q. In his Curriculum Vitae which is Exhibit 192 it notes he gave a presentation on Sudden Infant Death Syndrome at the International SIDS Conference in Baltimore in 1982.

Were you present at that conference?

A. No, I was not.

Q. And he has done other writings including chapters in books on SIDS, articles on SIDS. Have you done any writing on SIDS?

A. No, I have not.

Q. Are you aware of Dr. Bain?

A. I know who he is and I met him for the first time last month when I was at the digoxin workshop here. I had read his report a year ago.

Q. Are you aware of Dr. Bain's qualifications in the field of cardiology?

A. I am aware that he is an eminent cardiologist. I don't know specifically his CV.

Q. Well, let me refer you to Dr. Bain's report which is Exhibit 148 that you indicated you have read.

A. I haven't read it in the past year.

Why doesn't Shatner apologise for
his misleading statement?



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Q. No, no. Do you have it with
you?

4

5

6

A. I am not sure I have it here.
It probably would be best if there was a copy that
I could refer to.

7

8

9

MR. SCOTT: Just so that it will be
clear, I don't want to confuse the expertise of
Dr. Bain but he is not a cardiologist at all. I
think that should be made clear for the record.

10

THE COMMISSIONER: All right.

11

12

13

MR. SCOTT: I accept it on his behalf
that he is eminent but I cannot accept Dr. Kauffman's
statement that he is an eminent cardiologist.

14

THE WITNESS: I will withdraw that
statement.

15

16

MR. SCOTT: Leave the eminent part
in. I will have to report to him.

17

18

19

MR. STRATHY: Q. Doctor, if you
would turn to page 17. It is not particularly
well numbered.

20

A. Of the Bain Report?

21

Q. Bain Report.

22

23

24

25

THE COMMISSIONER: That is the page
between 16 and 18 surprisingly. Sometimes you find
in this report that that doesn't hold true. In



Kauffman, cr.ex.
(Strathy)

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2 this case it does.

3 MR. STRATHY: Q. Do you have that,
4 Doctor?

5 A. Yes, I do.

6 Q. At the top of the page

7 Dr. Bain is summarizing the case of Hines and he
says:

8 "The episodes described at home prior
9 to this baby's admission to the North
10 York General Hospital are consistent
11 in every way with near missed Sudden
12 Infant Death Syndrome."

13 Now do you agree or disagree with that
14 statement that they are consistent in every way?

15 A. I would not totally agree with
that as I read the chart.

16 Q. For the reasons that you have
17 given?

18 A. Yes, because the baby
19 apparently was not well and was not feeding well
20 for several days before this episode occurred which
21 indicated he was sick for some reason and then he
22 did have the apnea. But as I said I think if he
23 would have had the apnea without the other things
24 occurring before and subsequent to his admission

25



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(Strathy)

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2 I could accept a near missed-SIDS I think fairly
3 readily, but these other things make me less ready
4 to accept as strong a statement as this.

4

5 Q. What about the next statement:

6 "Such babies are at extremely high
7 risk of dying in the weeks following
8 such an episode."

8

9 Are you prepared to accept that?

9

10 A. I think a baby who has apnea,
11 documented apnea, is at increased risk, yes.

11

12 Q. What about babies who have
13 had a near missed-SIDS. Are they at an extremely
14 high risk of dying?

15

16 A. I would think they are at an
17 increased risk, yes.

18

Q. And he says:

19

20 "The mode of dying in Hospital was
21 again completely consistent with SIDS."

22

23 Do you accept that statement?

24

25 A. I don't totally accept that,
26 no.

27

28 Q. What is your reservation?

29

30 A. My reservation again is that
31 this was a baby who had other symptoms and findings
32 before he came in, several days before he came into
33

34

35



1

2 the Hospital. He continued to have some arrhythmias ---

3 Q. Well, just before you go on ---

4 A. I am sorry.

5 Q. He is talking about the mode
6 of dying in the Hospital. I am simply asking if
7 the mode of dying is consistent?

8 A. Well, let me refer to the
9 description if I may of his mode of dying.

10 I get the details of the cases
11 confused and so I really should review the
12 description before I answer you definitively.

13 Q. All right.

14 A. If you can refer me to the
15 appropriate pages?

16 Q. Yes.

17 A. I remember when I read it
18 I didn't think that it was but I can't give you
19 specific answers without referring to it.

20 Q. Well, if you look at page
21 36, you have got the arrest note, and before that,
22 the page before you have got the nurse's note.

23 A. If we can go back a couple
24 of pages before that.

25 Q. Yes.

26 A. Because this is important in



1

2 my decision making, and that is he is described to
3 have a widely variable heart rate with changing
4 heart rate varying from bradycardia to ---

5

Q. Where are you reading from?

6

A. I am sorry, page 30. Page 34.

7

Q. I think that is on the 6th

of March.

8

9

10

11

12

A. Right. Leading up to - he

was admitted as you know with the history of
looking sick, feeding poorly several days before
he came in and then he had the episode of colour
changes and apnea at home. Then he was admitted.

13

14

15

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17

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19

He is described the 6th of March

as having bouts of tachycardia, 185 to 150,
bradycardia of 50. Respiratory rate varying. Tires
easily with feeds. Gagged. Became quite mucousy
which means he had a lot of mucus in his upper
mouth and upper respiratory tract I suppose. Cleared
his nasal congestion and then he was in no apparent
distress according to that note after that.

20

21

22

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The next note is his heart rate was
143 to 178 regular. And then if we go on ---

Q. Just before you go on, do
not those notes indicate that the child seemed
to be in relatively sound stable condition?



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A. Well, not really.

3

Q. What do they indicate?

4

A. That he is having changing
heart rate with bradycardia episodes intermittent ---

5

Q. This is on the 6th?

6

A. Yes, intermittent with
7 tachycardia.

8

Then we go on you see further notes
9 to that effect on 3/8.

10

Q. I am sorry, 3/8?

11

A. On page 35. I am sorry,
12 8/3.

13

Q. That is the 8th of March?

14

A. Right. The 8th of March on
15 page 35. He has some tachycardia but his heart
rate was regular.

16

At that time he was feeding well
17 but then at 0300 he wasn't interested in feeding.
Went back to sleep. He is described as having a
18 congested chest with a loose productive cough.
19 And then at 4:10 he arrested according to that note.

20

On page 36 where we started this
note says that the arrest was called at 0425. He
22 suddenly developed an arrhythmia, no effective
23 output on his monitor. It looked like he had
24

25



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8 2 ventricular fibrillation. Very irregular in size
3 and shape. He was oxygenated and so forth in the
4 attempt to resuscitate him.

5 The picture you get from both the
6 summary and his history on admission and the course
7 as described in the chart as you go through it is
8 a baby that was not well prior to his admission.

9 Q. Yes.

10 A. Was acutely ill. A baby who
11 remained ill and was having problems with feeding
12 and some changing heart rate during his hospitaliza-
13 tion, and then suddenly went into cardiac arrest
14 with ventricular fibrillation and could not be
15 resuscitated.

16 Now to me that is not typical of
17 a SIDS death. It is typical of a baby who had
18 some underlying serious illness.

19 Q. Let's just stop at the baby's
20 death which you refer to as cardiac arrest with
21 ventricular fibrillation and could not be resuscitated.

22 Would you not agree that that mode
23 of dying as Dr. Bain says is completely consistent
24 with SIDS, leaving aside the previous condition?

25 A. Well, the clinical description
26 of SIDS death is a baby who has been thought to be



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in normal health and is without any explanation
found dead with no sign of struggle. May have
a little bit of emesis in their mouth but really
no sign of a struggle and no explanation for the
death. SIDS is really a diagnosis of exclusion.

6

Q. That is your understanding?

7

A. That is my understanding.

8

Q. And just stopping you, Doctor,
and the question I asked you before we got into
this, I asked you about the mode of dying in the
Hospital being consistent with SIDS. Just dealing
with the mode of dying.

12

A. If you ignore everything else
and say that cardiac arrest could be consistent
with SIDS, I would agree with you.

15

Q. I don't think that even
Dr. Bain is suggesting that and I was not suggesting
that. I asked you about what you refer to as
cardiac arrest, ventricular fibrillation and could
not be resuscitated. Would you agree that that
is consistent with SIDS?

20

A. If you want me to consider
that along with his short hospital course I couldn't
agree that it is totally consistent, no.

23

Q. If you look at the next

24

25



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2 sentence it says:

3 "It is documented that 75% of SIDS
4 deaths occur during the night and
5 early morning hours."

6 A. Yes.

7 Q. Do you know sufficient about
SIDS to agree or disagree with that?

8 A. I think I would agree with
9 that.

10 Q. Then it goes on:

11 "The pathological findings of the
12 thickening of pulmonary arterioles,
13 persistence of brown fat, gliosis in
14 the brain. In the region of the vagal
15 nuclei and extra medullary hematopoiesis
are the pathological findings of SIDS."

16

17 Are you able to agree or disagree
18 with that?

19 A. I would agree to the extent
20 that these are pathological findings that are seen
21 in babies, some babies who die and are thought to
22 be SIDS babies. I would not agree that every baby
23 who dies of so-called SIDS has these findings and
24 I would not agree that these findings are

25



1

2 definitively diagnostic of SIDS.

3 Q. Presumably you would agree,
4 though, people actually present at the autopsy,
5 people who actually performed at the autopsy, would
6 be in a better position than you to assess what
7 those autopsy - to assess and interpret the autopsy
8 findings?

9 A. Well, depending on the
10 validity of their description.

11 Q. Exactly.

12 A. Yes.

13 Q. Indeed there may well be
14 things that they saw at the autopsy that aren't
15 shown in the description?

16 A. Well, I hope they are complete.

17 Q. Well, indeed, but presumably
18 in the course of a page or two it is not possible
19 to record everything that one sees and presumably
20 every doctor depends to some extent on eyes and
21 hands and so forth in making his diagnosis?

22 A. I assumed when I read the
23 autopsy report that they had described all the
24 pathologically important findings. If they didn't
25 then I could be in error.

26 Q. Once again I assume that a



1

2 .pathologist because of his training and experience
3 would be in a better position than you to interpret
4 those findings?

5 A. He would be in a better

6 position to describe the findings. I am not
7 necessarily sure that he would be in a better
8 position to clinically interpret those findings.
9 Certainly equally but not better.

10 I am not sure, but he certainly could
11 describe the findings better than I could.

12 Q. But you would be prepared to
13 put yourself on the same plane as Dr. Becker in
14 terms of interpreting?

15 A. Interpreting what I saw in
16 the ~~microscopy~~?

17 Q. Interpreting the autopsy
18 findings as they relate to SIDS?

19 A. I don't think I would compete
20 with him in terms of pure technology. I am a
21 clinical paediatrician. He is a pathologist.
22 I see SIDS from one side of the death and he sees
23 it on the other side so I think we probably would
24 view it from a different perspective. And I certainly
25 wouldn't compete with him as a pathologist, no.



BmB.jc

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Q. Can I ask you then to turn to the case of Justin Cook. Once again, we have some information from Mr. Cimbura. Do you recall when you received Mr. Cimbura's various reports?

A. I think I received different ones at several different times but I can't give you specific dates. I might be able to eventually go through files and pick out cover letters that would indicate time of transmission if that is important.

Q. Well, that's all right. Was it before you prepared your report for Mr. Wiley?

A. Oh, yes. Other than the information that I didn't have at hand that I had the basis on which I made my revisions.

Q. If you can look at page 2 of Mr. Cimbura's first report, it is Exhibit 95A and it is dated January 11, 1982. Do you have that, Sample T22?

A. Yes.

Q. Near the bottom.

A. Yes.

Q. There is a reference to fluid reported to be chest fluid and found to contain 70 nanograms per millilitre of digoxin and then it goes on to make reference to a .08 milligrams per cent of



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E.2

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2 Lidocaine. Do you see that?

3 A. Yes.

4 Q. Now, Doctor, there is no
5 reference in the chart of Justin Cook to that child
6 having received Lidocaine. Were you aware of that?

7 A. I was aware that there was no
8 reference in the chart that he had received Lidocaine
9 and I was aware that the Lidocaine had been detected
in this fluid, yes.

10 Q. Do you have an explanation
11 for that?

12 A. I don't have a specific
13 explanation. There are several possibilities that I
14 could speculate; one is that during a resuscitation
15 effort, or shortly before one of the procedures, is
16 to put in a cutdown frequently to gain access to the ...

17 Q. Into the vein?

18 A. ... into the vein. It is
19 common practice to inject Lidocaine at the site of
20 the cutdown to give local anaesthesia. Now, that
21 could produce - of course, that is absorbed and it
could produce a blood level of Lidocaine.

22 Q. Presumably, just stopping you
23 for a moment, that should be charted however if that
24 is done?

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A. Yes. Well, it wouldn't

necessarily. You know, in the course - I don't know the procedure and I wasn't there but it wouldn't necessarily be charted because if everybody else - it is not considered in that context to be one of the resuscitation medications. The surgical resident would simply be anaesthetizing the skin during the cutdown and getting the catheter in.

The other possible way it could be

administered would be if it had been administered as a part of the resuscitation effort to attempt to

convert the ventricular fibrillation. Lidocaine is also used intravenously to decrease heart arrhythmias.

If it were used that way I would have expected it to have been charted.

Q.

?

A. I would accept that.

Q. Are there any other hypotheses you have as to why that Lidocaine was detected?

A. Not off the top of my head, no.

Q. Let me suggest one to you and that is the possibility that the drug was given in



E. 4

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2 error at some point during the Hospital, say, possibly
3 at the time of the arrest?

4

A. That the Lidocaine was given
5 in error?

6

Q. Yes.

7

A. That is a possibility, I suppose.

8

Q. So then we really have three
9 possibilities. It may have been given when the cut-
10 down was done, it may have been given at the time of
11 the arrest but not charted, or it may have been given
12 at some time through inadvertence and not charted?

13

A. I would agree with that.

14

Q. In the context of the arrest,
15 Doctor, and the possibility that it was given during
16 the arrest intentionally but not charted, do you see
17 that as a distinct possibility that in the tension
18 and hurry of the arrest a drug might be given amongst
19 many other drugs and the fact omitted from the chart?

20

A. I would accept it as a
21 possibility. I have no way of assessing the
22 probability of it because I am not at this Hospital,
23 I know nothing about the resuscitation procedures and
24 so forth.

25

Q. I appreciate that.

26

A. But I would accept it as a
27 possibility.

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E.5

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Q. Well, surely from your general knowledge as a physician, and particularly your specific knowledge as a pharmacologist, you are familiar with medication errors and the ways in which they occur?

A. Unfortunately, yes.

Q. Well, unfortunately in the sense that unfortunately they do occur?

A. That is what I meant, yes.

Q. And as long as we have people administering drugs we are going to have drug errors, obviously?

A. I think that is unfortunately true. We try to minimize it but they do occur.

Q. Well, part of the business of a pharmacologist is to know about drug errors and how they do it?

A. That would be a part of every physician's responsibility.

Q. Well, true enough, but a pharmacologist I would think because of his concern about drugs is perhaps more specifically interested in that area than others?

A. They could be.

Q. Well, indeed, you have written



E. 6

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2 about the subject. The unit does system, for example,
3 which as I understand it is a way of minimizing drug
4 errors?

5 A. Yes, it is.

6 Q. And as a pharmacologist, you
7 are familiar with the circumstance that in arrest
8 situations, again, unfortunately medication errors do
9 occur?

10 A. They can occur, yes.

11 Q. So, in dealing with this
12 particular child, it is possible, and let us put it
13 no higher than that, that one of two things happened
14 during his arrest; it was either possible that he
15 was given Lidocaine intentionally and it wasn't
16 charted or possible that he was inadvertently given
17 Lidocaine?

18 A. Or that he received it as a
19 cutdown.

20 Q. Fair enough, any one of those
21 possibilities?

22 A. Yes, and I have no way of
23 assessing the relative probabilities of those
24 possibilities.

25 Q. Fine. Now, dealing with Justin
Cook and your various hypotheses about the dose that

#5!



E. 7

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2 the child might have received. As I understood it,
3 your range was, and I'm going to do it in terms I can
4 understand in terms of vials, which is a bit simpler.
5 You posited a range of between one adult vial and
6 death occurring within an hour of the injection to
7 8-1/2 adult vials with death occurring within six
hours after the injection. Do you see that?

8

A. I think that reflects my
9 minimum and maximum estimates given the assumptions
10 I outlined, yes.

11

Q. All right. And your evidence
12 really was that your best estimate was that it was
somewhere in between?

13

A. Yes. I didn't think it was
14 less than an hour but I thought it was probably not
15 much longer than three hours because of the elevated
16 serum and the high fresh tissue levels.

17

Q. And then I would like to ask
18 you to turn to your report to Mr. Wiley at page 5. Can
19 you get that in front of yourself.

20

A. The first report, right?

21

Q. Yes.

22

A. Okay.

23

Q. And there, just down from the
top of the page, the third line of page 5, you say?

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E. 8

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"The presence of a high concentration of digoxin in ventricular myocardium indicates that at least some distribution between blood and tissues occurred between the time of dose and time of death. Therefore, it is unlikely that death occurred less than one hour following the dose as assumed in the estimate of a minimum possible dose."

And you have just told us about that.

"On the other hand, it is difficult to conceive of the infant surviving very long with such a high concentration so that the onset of critical symptoms probably occurred within two to three hours of the delivery of the dose."

Now, let's just stop there for a minute. Are you able to say when it was in Cook that you viewed the onset of critical symptoms as beginning?

A. Well, let me look at the chart and times in my notes.

Q. Thank you.

A. I don't have an index chart, so



E.9

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2 if somebody can guide me to that part of it I would
3 appreciate it.

4 Q Well, maybe we can do this, I
5 don't know if it will help you. But if you go over
6 to page 3 of your notes to Mr. Wiley you point out
7 in the first paragraph that at 3:30 a.m. on 22/3/81
8 he became irritable and developed increased cyanosis,
9 had a generalized seizure and developed bradycardia
10 followed by ventricular fibrillation approximately 30
minutes later.

11 A The timing for the serum
12 sample of course has to be timed at the time when the
13 sample was taken but the time of critical symptoms
14 I would agree, and I haven't found it in the chart
15 yet, but I think I would agree based on my comments
16 in the letter, I would have timed it at approximately
3:30 a.m.

17 MR. OLAH: Page 29 of the chart,
18 Doctor.

19 THE WITNESS: Page 29. Well, on page
20 27 there is a note that says "Child well until 3:45
21 and then increased cyanosis of extremities. Breathing
22 okay, heart rate stable, oxygen increased."

23 And at page 29 then it gives the time
24 of 3:45 again. So, the things changed it looks like
25



E.10

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2 at about 3:30 to 3:45 a.m.

3

4 Q So, can we take that as being

the onset of critical symptoms?

5

6 A I think so, I think I would

7 agree to that.

8

9 Q So, you are using your two to
10 three hour estimate on page 5, we would be talking
11 back to 1:45 or 12:45 then as the time of the dose?

12

13 A Approximately that, yes.

14

15 Q So, somewhere between 12:45

16

17 and 1:45 is your best estimate then?

18

19 A I think the other day I timed
20 my estimates based on the serum concentration from
21 the time it was drawn. So, that makes that time a
22 little different and I would have to do the arithmetic.

23

24 Q Well, that's what I was
25 wondering about. I think yesterday or the day before
you said that you thought it was most likely one to
three hours prior to the time of the sample, somewhere
between one and three hours prior to the time of the
sample. The time of the sample we have been told is
4:30 a.m.

26

27 A All right, it was taken right
28 during the resuscitation effort, right.

29

30 Q That's right.

31

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A. Right.

2

Q. So taking one to three hours
prior to 4:30 a.m. that places anywhere between 1:30
a.m. and 3:30 a.m.?

3

4

A. And if we time it from the
sample we move an hour over.

5

Q. Well, that's right. But what
I'm trying to find out, Doctor, is now we've got
several ranges here. We've got 12:45 to 1:45 and
then we've got 1:30 to 3:30 as being ranges. What I'm
trying to find out is where you see the range being
today. Maybe I can put one more thing in front of
you.

6

7

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15

A. Okay. I'm not sure I can be
that precise on the range. You know, these are best
estimates.

16

Q. Well, okay.

17

18

19

20

A. I know it is important to you
and I'm not trying to hedge, it is just that we have
to be very careful with all the variables that we
are dealing with to try to tie it down to an hour.

21

22

23

24

25

Q. I think we all want to make
sure that before you leave us hopefully tomorrow we
are at least aware of what the uncertainties are and
what the ranges are and that we are not stuck with



E.12

1

Offensive!

2

one thing as being the gospel from Dr. Kauffman.

3

A. Right.

4

Q. I don't think you would want
to leave us with that.

5

A. I understand that.

6

Q. So, can I ask you to look at
your case report to the people at the Centers for
Disease Control. This is your little three-page
summary.

10

THE COMMISSIONER: What exhibit is that?

11

MR. STRATHY: Miss Cronk has the tabs,
I don't have tabs on mine.

13

MS. CRONK: Tab 37 I believe, sir.

14

MR. STRATHY: Tab 37.

15

THE WITNESS: You are looking at the
score sheet for Cook?

16

MR. STRATHY: Q. Well, I'm looking at
the ---

18

A. The last page of that scoring
sheet?

20

Q. Yes. Do you have that, Doctor?

21

A. Yes.

22

Q. Just to clarify for me, are
these your words on this page?

23

A. To my knowledge these were my

24

25



E.13

1

2 pencil written notes on the back page. To my knowledge,
3 they typed them verbatim as I wrote them. I have
4 never seen my pencil written notes since I wrote them
5 and to my knowledge they retyped them verbatim. I
have no reason to think otherwise.

6

7 Q. I'm afraid I missed your
evidence yesterday morning but do I understand that
8 these were prepared separately from your letter to
9 Mr. Wiley?

10

11

A. Yes, these were prepared
approximately one month prior to my drafting the report

12

13

sheet at the last paragraph:

14

15

16

17

"Digoxin was likely administered
within one hour of the onset of
terminal symptoms, although, this
is speculative."

18

19

20

21

22

23

24

25

So, that puts us somewhere in the
range of 2:30 to 3:30, within one hour of the onset.
So now, Doctor, we've got three different ranges. I
guess what we all need to know is, is it your
evidence today that it could reasonably be somewhere
within that time, anywhere from 12:45 to shortly
before the onset of the terminal symptoms?



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DMra 3

A. I think-one of the problems
I have is, and I think other people are having it too,
is defining death in this child and some of the others,
because death, actually, the event actually occurred over
an hour or more period of time, so it is difficult to
define. You can define the time in some of them when
things seem to suddenly change; you can define the
time when the resuscitation team finally said, we can't
do anymore and stopped; but there is an intervening
time which is really a no-man's land in terms of
the time of death.

So at the time I wrote this I don't
think I was consciously trying to be as precise as you
are asking me to be today, obviously. In terms of
trying to relate in some way an estimate, trying to
relate an estimate of a possible dose to the serum
concentration, I think I have to use the time that that
sample was obtained.

Now in terms of trying to make any
kind of relationship to the tissue concentration, I
think I have to be more variable because we have got,
not a specific moment in time of death occurring, but
a period of time. So I suppose that I would have to,
if you are really going to pin me down, I would have to
say that the critical symptoms spanned a period of an

24

25



1

F2 2 hour or so, and they started at about 3:45 and ended
3 with the end of the resuscitation effort at 4:30, is
4 that correct?

#6
4-56 Q. Approximately.

A. Yes. So I would have to say in
6 terms of considering the tissue concentrations I have
7 to take that span of time over which death was occur-
8 ring as a part of the whole time period in which I
9 estimate a dose could have most likely been given. I
10 don't know if that is helpful to you.

Q. Frankly I am not sure that it
11 does help me too much. I understand what you have said
12 about the problems of trying to pinpoint death. What
13 I am really trying to get at, doctor, and I think for
14 the Commission's purposes it is important, is some
15 idea of the range as to where in your best estimation,
16 and if you want to make it a broader range than you
17 have before that is fine.

A. Let me try to get at it this
18 way. I think because of the high tissue concentrations
19 it is quite unlikely that a bolus was given less than
20 an hour, because there had to be some time for distri-
21 bution to have taken place. Now more than an hour
22 becomes more difficult for me to define with the same
23 degree of certainty. I think that if this was

24

25



F3

1
2 digoxin intoxication, and I think it was, that the
3 effect of the digoxin was probably starting at this
4 3:45 period. So then the sample could have been -- I
5 mean the dose could have been given, my best estimate,
6 it could have been given some time during the three
7 hours prior to that. It could have been a little
8 longer, but I have a hard time getting much longer
9 than that because I would think that kind of dose
10 would have caused some severe symptomatology in a
11 somewhat shorter time than three hours. The literature
12 indicates that this can be variable enough that I can't
be more certain than that.

13 Q. So when you are talking about
14 one hour as being the boundary, if you will, you are
15 talking about one hour from the time of death, the
16 actual 4:30 to come to that?

17 A. Well, not necessarily. The
18 problem there is you don't know how much distribution
19 may have taken place during resuscitation. You know
20 that cardiac output is lousy during that time, it
21 really is very poor. So much less blood is profusing
22 most of the tissues during that time, but it is con-
23 ceivable that some digoxin could be carried to
24 tissues during that intervening time when death is
25 occurring, although it would be less if profusion is

#7!



1
F4 2 normal I would predict.

3 Q. Let me put it to you this way.
4 Suppose we did have an IV bolus of one adult ampoule
5 at approximately 3:30, and you then have at a certain
6 time before the arrest, while the child's system is
7 working, an arrest with the various manipulative
8 efforts that we have seen taking place ultimately
9 death at or shortly after 4:30. Would that in your
10 view account for the both the serum and the tissue
11 levels?
12

13 A. I think it is much less likely
14 that it would account for it than for the dose being
15 given a little longer than that before the event
16 occurred.
17

18 Q. But it is at least within the
19 realm of possibility?
20

21 A. Yes, a lot of things are
22 possible. I just have to say -- it is hard to agree
23 that a lot of things wouldn't be possible, I can't
24 really disagree with that, but I have been asked in
25 the past and I am being asked now you know to try to
make possibilities.

Q. That is fair enough.

A. On the likelihood scale I think
what you just suggested is less likely than receiving



1

F5 2 the dose more than that, a little more than an hour.

3 MS. CRONK: I'm sorry, Mr. Commissioner,
4 I don't like to interrupt my friend. My friend may
5 have forgotten this and I don't know what effect it
6 has on the doctor's thinking, and it may be relevant
7 for Mr. Strathy's purposes.

8 The sequence of events recorded in
9 the medical chart is that the Code 25 is called at
10 4:20; the sample is taken at 4:30; the child is
11 pronounced dead at 4:56. Now obviously we don't know
12 when death occurred within that sequence of events,
13 I think the suggestion was made that the resuscitation
14 efforts stopped at 4:30, that is not the case.

15 MR. STRATHY: Thank you. I am grateful to Miss Cronk.

16 MS. CRONK: It occurred some 20, 25
17 minutes later.

18 MR. STRATHY: Q. Let me just put
19 this to the doctor, then. Doctor, assuming again that
20 the IV bolus was one adult ampoule, that it had between
21 3:30 and 4:20 been distributed into the tissues before
22 the Code 25 was called, you then have the Code 25 at
23 4:20 and the sample at 4:30, that is the serum sample.

24 A. That is about an hour.

25 Q. And then subsequently post



1
F6 2 mortem tissue samples.

3 A. Right.

4 Q. In that scenario do you see
5 the one adult ampoule at 3:30 being somewhat more
6 likely than what you have suggested to us?

7 A. You see the one adult -- I
8 understand what you are saying, I think the one adult
9 ampoule theory is even less likely, it becomes less
10 likely the further away from death we move, or further
11 away from distribution, possible distribution. Because
12 the only way that one adult ampoule hypothesis in my
13 mind would work is if you have virtually no distribution
14 to tissues, that is my memory of those, and that
15 assumes no tissue distribution.

16 Q. So you say that your one adult
17 ampoule theory --

18 A. At 3:30 it becomes even less
19 likely with the times that we were corrected about.

20 Q. But it becomes more likely if
21 it is administered closer to death?

22 A. If it was given just before
23 circulation stopped, moments before circulation
24 stopped, then I would accept it, yes.

25 Q. Let me put to you this. Would
you be prepared to accept one adult ampoule, I gather



1
F7 2 you would, at or very near the time the circulation
3 stopped?

4 A. I think so, yes.

5 Q. May I ask you this. Suppose
6 that one adult ampoule is given intracardiac, would
7 that account in your mind for the tissue levels in the
8 case of Cook?

9 A. I think if there were no
10 circulation, even if -- you are talking about injected
11 into the chamber of the heart?

12 Q. Yes.

13 A. I would have to think about that.
14 I think if we are continuing the assumption of no
15 effective circulation I would have a hard time even
16 under those conditions accepting the kind of concen-
17 trations in fresh autopsy tissues that were described.

18 Q. Let us -- I am sorry.

19 A. I am sorry, go ahead.

20 Q. I was going to ask you to add
21 the hypothesis of cardiopulmonary resuscitation taking
22 place.

23 A. Well then we have circulation,
24 some sort of circulation, we don't know how effective
25 but some sort of circulation.

Q. That is the whole purpose of



Kauffman
cr.ex. (Strathy)

1

F8 2 cardiopulmonary resuscitation?

3 A. Right.

4 Q. So in that hypothesis a direct
5 intracardiac injection of digoxin at/or -- or at the
6 time of the arrest followed by cardiopulmonary
7 resuscitation, would that in your mind explain the
tissue levels, or could it explain the tissue levels?

8 A. I suppose it is possible, I
9 think it is somewhat difficult. Because as you know
10 distribution takes place over a period of hours with
11 a half life of 30-60 minutes under normal circulatory
status.

12 Q. That is talking there about
13 distribution where the drug is administered either
14 intravenously or orally?

15 A. Right. But still even with --
16 you see when you do an intracardiac injection you
17 never know for sure whether you have put the needle
18 into the right ventricle or the left ventricle. If
19 you make your injection into the right ventricle; now
20 Cook was such an anomalous baby that this does not
21 all necessarily apply, because I think this baby had
22 a single ventricle with a small right ventricle out-
flow tract, am I correct in that?

23 Q. Probably more correct than I

24

25



Kauffman
cr.ex. (Strathy)

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F9 2 can tell you.

3 A. With obstruction to her
4 pulmonary artery, so the abnormal anatomy makes it
5 difficult to speculate. But under those kinds of
6 conditions and the condition she was in with markedly
7 reduced pulmonary flow, most of the cardiac output
8 was going out to her body rather than to her lungs
9 at that point in time, what cardiac output there was.
10 So the blood injected into the single ventricle I
11 would predict would be distributed out to the body
12 before it returned and got back to the lungs to come
back into the heart again.

13 I don't remember specifically what
14 was described about the anatomy of her pulmonary
15 arteries, because the digoxin to get into the heart
16 muscle would have to be pumped into the coronary
17 arteries which profuse the heart muscle itself. I
18 don't remember if she had anomalous, any evidence of
19 anomalous pulmonary artery takeoff or not, I don't
think that that was described, I don't recall for
sure.

20 Q. Is it not possible in the
21 proposition that I have suggested to you that in the
22 course of administering the digoxin intracardiac there
23 is also contamination of the surrounding tissue with

24

25

Is there the slightest w. to suggest
that dig may have been given
(presumably in sugar) by ~~to~~ in ha-
emocaudine injection?
Even if it were, ~~is~~ is it likely that
it could account for the high
myoconducin concentrations?



1
F10 2 digoxin?

3 THE COMMISSIONER: I'm sorry, in the
4 course of administering --

5 MR. STRATHY: Digoxin intracardiac.

6 A. You mean in general making a
7 cardiac injection?

8 Q. Yes.

9 A. There's a possibility of
10 contamination of tissue of the pericardial sac with
whatever you are injecting, yes.

11 Q. Exactly.

12 A. I think that is a possibility,
13 yes.

14 Q. Thank you. Doctor, with
15 respect to Justin Cook we have the report of Dr.
16 Hastreiter which you have I think either seen or --

17 A. You mean the clinical summary
18 that he prepared?

19 Q. Yes, he has prepared, do you
have that?

20 A. I can pull it out in just a
moment.

21 Q. I am not sure you have the
22 page numbers as I do.

23 A. No, I don't.

24

25



Kauffman
cr.ex. (Strathy)

1

F11

2

Q. I am going to show you page 176.

3

A. Dated the 22nd of March?

4

Q. Yes.

5

A. I may have it.

6

Q. It is page 176 of Exhibit 264

7

and I commence at the bottom of the page, near the
middle of the paragraph where Dr. Hastreiter says:

8

"However the post mortem findings of
high concentrations of digoxin in
blood are very significant because of
the fact that post mortem levels will
usually tend to be considerably higher
than ante mortem blood levels, a
demonstration of very high ante
mortem blood levels is even more
significant. Digoxin is not indicated
for this infant and had never been
ordered by the physicians in charge.

18

If one assumes that the infant
was given one large dose of intravenous
digoxin, the most likely time for this
to have occurred would have been just
prior to the infant's terminal
deterioration at 0330 hours."

19

23 I take it for the reasons that you

24

25



1

F12 2 have I just given, you would disagree with Dr. Hastréiter
3 as to the likelihood of that happening?

4 A. I don't know how strongly
5 he feels about it, but I would disagree for the
6 reasons I have stated with the statement as it is
written here, yes.

7

8 Q. And if you could turn over the
page, I don't know if you have a further page on
9 Cook.

10

A. I have page 2 of that.

11

12 Q. All right. "It would have been
extremely difficult for the infant
13 to have maintained a plasma level
of digoxin of about 70 nanograms per
14 ml. for any sustained period of time
15 without the development of fatal
16 disturbances of the heart rhythm
17 and death."

18

19 Now that is something that troubles
20 me, doctor, because I would have thought simply from
21 lay terms that that makes a lot of sense, that it
22 would have been extremely difficult for the child to
23 have maintained a level of digoxin of 70 nanograms
24 per ml. without showing those disturbances. Do you
25 agree or disagree with that?



EMT.jc
G 1

2 A. I haven't located the sentence
3 you are reading yet.

4 Q. Well, maybe --

5 A. I got the page here.

6 Q. Dr. Hastreiter seems to have
7 generated several reports so let me just show you.

8 A. Oh, I was on the wrong page I
think.

9 Q. Maybe my pages are out of order.
10 It is the top paragraph here.

11 A. Oh, yes.

12 I don't think that is totally
13 inconsistent with what I have said depending on what
14 he means about "sustained period of time".

15 There are - some of the case reports
16 in the literature on digoxin poisoning where it is
17 known that a child was poisoned where children have
18 maintained certain concentrations in this range for
19 a period of several hours without dying or maybe not
even showing --

20 Q. A range of 70 nanograms per
21 millilitre?

22 A. There is a case report that
23 was treated with FAB fragments a year or so ago, a
24 two or two and a half year old child, where the

25



G.2

1

2 pre-treatment level was over 100 and the child survived.
3 With this treatment. But he wouldn't have otherwise.
4 But he had received that dose several hours prior. So
5 I don't know what he meant by "sustained period".

6 I agree with that if he would have
7 included in that a couple of hours. If he is talking
about several minutes I would not agree with it.

8

9 Q. He seems to be talking about
10 a relatively short time because he says "this is the
11 basis for my statement that ... assuming laboratory
12 values are correct, digoxin was given shortly before
the infant's terminal episode of deterioration".

13

14 A. I assume he is talking, when
he says "terminal episode of deterioration" around
3:30, 3:45.

15

16 Q. That is what it seems to
17 indicate. So you don't necessarily go along with that
observation?

18

19 A. Well, I am not sure - you know,
I am being asked to be a little more precise than he
20 is in his wording here so I am not sure I disagree
with it.

21

22 Again if he means moments before that
I would tend to disagree with him. If he is talking
23 about in terms of sustained period several hours I
24

25



G. 3

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2 would not disagree.

3 Q. A fair reading I think on
4 page 1 he says "just prior to" and on page 2 of 3 he
5 says "shortly before".

6 Now I take that to mean at least
7 a relatively short period of time.

8 A. I think we interpret "very
9 shortly before" in terms of minutes let's say. Then
10 I would view that as less likely than a little beyond
11 that or prior to that time.

12 Q. I think you do agree with
13 Dr. Hastreiter in his No. 3 on the third page, the
14 middle of the page. It is 177 in my book. He thinks
15 the most likely route of administration is IV bolus?

16 A. Yes, I agree with that.

17 Q. Just by the bye, from your
18 previous answer I take it that there is really no
19 specific level of digoxin that you would regard as
20 necessarily fatal?

21 A. Well, the illustration I just
22 cited would have been fatal had not the child received
23 the antibody treatment.

24 Q. That is a level of a hundred?

25 A. Yes. This child was maintained
26 with resuscitation efforts for two hours before he



G.4

1

2 received the antibodies and then he received the
3 antibodies and he recovered in 35 minutes. So he
4 would have died with that level had he not been
5 treated with antibodies.

6

Q. But is there a range that we
can look to that says, all right, if you are within
this range digoxin is necessarily fatal for a specific
child?

9

A. I don't think we can define
a specific - I don't think we can say a specific level
is toxic or not toxic unless it is well above a
concentration that has been consistently associated
with death.

13

14

Q. What are you talking about?

What level?

15

16

17

18

A. That is difficult to say. The
literature describes levels anywhere from - that may
have been associated with death - my recollection is
anywhere from maybe 10 up to anything above 25 or 30.

19

20

21

22

23

24

25

It is extremely variable, and there
are also instances of patients having levels in the
neighbourhood of 10 or 12 and not showing - not dying
certainly and maybe not even showing much signs of
digitalis toxicity. So there is a tremendous amount
of overlap. That is what makes this drug so difficult



G.5

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2 to try and make any predictions about it.

3

4 child it is difficult to say whether a level is or is
5 not going to be fatal.

6

7 A. I think there are some levels
8 that you could say that is likely going to be fatal.
Once it starts distributing to tissues.

9

10 Now I think if I was told that a child
11 had a level of 50 or 60 or 70 or above within an hour
12 or two after administration, receiving a dose, I
13 would expect uniformly to see serious toxicity that
14 would be very likely fatal if no intervention were
15 taken.

16

17 Q. Is it the digoxin in the serum
18 that kills the child or is it the digoxin in the
19 tissue?

20

21 A. I am not sure how you - what
22 you mean. I am not sure what you mean by that.

23

24 When we talk about serum concentrations
25 we use it because that is what is available to measure
the drug in, and we try to relate that concentration
to what, to the total amount of digoxin in the body
and make some interpretation on that basis.

26

27 Q. All right. I should be more
28 clear, then.

29

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G.6

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A. If you mean is it the molecules of digoxin in the serum that is toxic or is it the molecules of digoxin in the tissues that causes the toxicity, then it is the molecules of digoxin at the moment of time that are in the tissues that are actually at that time causing toxicity.

Q. So it is the digoxin as I understand it working in the tissue that has a therapeutic effect and presumably it is the digoxin working in the tissue that has a toxic or fatal effect?

A. Yes.

THE COMMISSIONER: Not only that, but it is also only in some tissues. Some tissues we have heard it has no effect at all.

MR. SCOTT: I can't hear the question, Mr. Commissioner.

THE COMMISSIONER: Well, it is probably just as well because it is not that good, but my understanding --

MR. SCOTT: When one of these chaps ask a question I don't need to hear it but if you ask it I would like to hear it.

THE COMMISSIONER: Well I understand that not only is there no effect of the digoxin in the serum but there is no effect of digoxin generally



G.7

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2 speaking in the tissues. It is only when it gets to
3 particular tissues and has the specific binding that
4 it has an effect. Now I may have misunderstood that.

5 THE WITNESS: I think digoxin gets
6 to all tissues.

7

THE COMMISSIONER: Yes. It doesn't
get specifically bound --

8

9

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THE WITNESS: A number of tissues
have sodium ATP ase in the cell surface to which it
can bind. We don't see with therapeutic doses, we
don't see overt effects from that binding in many
tissues.

For example, a lot of digoxin binds
to red blood cells. That doesn't seem to change
anything but it does bind to that specific enzyme in
red blood cells but it doesn't cause a measureable
effect that we know how to measure anything; it
doesn't seem to change anything for the patient when
it binds to red blood cells.

It binds to skeletal muscle. That
doesn't seem to make any clinical difference.

It binds to sites in the brain and
if the amount of digoxin gets a little too high you
can actually have central nervous systems, toxic
symptoms, from digoxin. And Dr. Wethering described

?Seizure
activity



G.8

1

2 that in England back in the 1700's.

3 You can actually have changes in
4 vision. So I wouldn't agree totally that digoxin
5 doesn't have an effect in a number of tissues, but
6 the ones that we usually see are those on the heart.
7 You can change - you can apparently have some effect
8 on kidney function and it is hard to sort out
9 whether that is indirectly due to increased heart
10 function or whether it is a direct effect on the
kidney.

11 It can have some effect on smooth
12 muscle and blood vessels various places. It can have
13 some effect on brain cells, so it does bind to a
14 variety of tissues both non-specifically and probably
specifically, but the effect is variable.

15 Q. It is really the heart tissue
16 that one is concerned about both for the therapeutic
17 effect and the toxic effect?

18 A. Primarily you can have severe
19 toxic effects for example from the effect on the brain
too.

20 Q. Just so that I am clear before
21 I leave today, understanding your answer, it is the
22 effect of the digoxin in the tissue that is the fatal
23 effect?

24

25



1

2 I said that also previously.

3 Q. But it is also important to
4 be aware of the qualifications that must be placed on
5 the other factors that one looks to in interpreting
6 digoxin data, specifically, the ambiguity, non-
7 specificity of the symptoms of digoxin intoxication?

8 A. Oh, I think that all has to
9 be taken into consideration, yes.

10 THE COMMISSIONER: Would this be an
11 appropriate time. I am sorry, were you finished
12 with Belanger?

13 MR. STRATHY: No, I am finished with
14 Belanger.

15 THE COMMISSIONER: Yes. Well, I
16 think we will take 20 minutes then.

17 ---Short recess.

18 ---On resuming.

19 THE COMMISSIONER: Mr. Strathy, I
20 hear everything you say, the witness hears every-
21 thing you say but apparently some of your fans do
22 not.

23 MR. STRATHY: Well, it is important
24 that the fans hear, Mr. Commissioner.

25 THE COMMISSIONER: Yes.

26 MR. STRATHY: So, I brought a microphone



1

8 2 over here.

3 THE COMMISSIONER: Right, okay.

4 MR. STRATHY: I will do my best.

5 Q. Doctor, briefly, to touch
6 on the case of Kristin Inwood, please, you have
7 mentioned the digoxin concentration of 491 nanograms
8 per millilitre found in the sample of serum and
9 you have expressed fairly serious reservations
10 about the integrity of that sample and the reliability
of that level?

11 A. Yes, based on what I was told.

12 Q. Does the level in and of
13 itself, 491 nanograms per millilitre, even apart
14 from what you have told, does it not appear to you
15 to be so high as to raise serious questions about
its reliability for that reason?

16 A. Well, when I revised my
17 report and the comments I made on the letter of
18 January 17 I think I alluded to that. I thought
19 the statement I made I think it was something to
the effect that it was difficult to conceive how
20 it would be feasible to administer the volume
21 necessary to contain an acute dose which would be
22 expected to produce a serum concentration of this
23 magnitude. Now, how much less than the 491 it was

24

25



1

2 I can't say but I agree it seemed to be such a
3 large number that it was difficult to explain.

4 Q. And given that fact and given
5 what we know about what happened to the sample, would
6 you agree that it is virtually impossible to say
7 what that sample means and what it represents?

8 A. I really don't know what
9 happened to that sample and for that reason it
is difficult to interpret it.

10 Q. Well, really, it is impossible
11 to interpret it, isn't it, unless we know what the
12 level actually is.

13 A. You can make some estimates
14 but it is impossible to interpret it with confidence,
yes.

15 Q. Well, you can say that 491 is
16 really 4 or you can say 491 is really 40 and you
17 can say what flows from those different concentrations
18 but I suggest to you it is really impossible to say
whether 491 is 4 or 40?

19 A. Well, I wouldn't agree with
20 you that it is likely that it is 4; 40 I would have
21 no quarrel with you; 4 I think is unlikely.

22 Q. How about 10?

23 A. I don't know.

24

25



1

2 Q. All right.

3 Now, can you turn please to the case
4 of Stephanie Lombardo. You discussed with Miss
5 Cronk yesterday the theory that the child's shunt
6 might have occluded and I simply wanted to put to
7 you this proposition that if the shunt did occlude
8 it would explain the child dying when she did and
the way she did. Do you agree with that?

9 A. Yes, that was one thing I
10 considered. Unfortunately, I have no information
11 one way or the other to confirm that but that was
12 one thing I considered, yes.

13 Q. And it would certainly explain
14 it, would it?

15 A. Yes, it could explain it.

16 Q. And indeed the absence of
17 a shunt murmur or the inability of the resident to
18 detect a shunt murmur just prior to death would
19 be consistent with the hypothesis that the shunt
did occlude?

20 A. Yes, it would.

21 Q. Thank you. Now, again,
22 previously on the levels in the case of Lombardo
23 which we know are from autopsy, exhumed autopsy
24 tissue, do you agree once again that those exhumed
25



1

11 2 levels, if indeed they do show digoxin or if they
12 3 mean digoxin, really tell us nothing about the amount
13 4 of the dose, the time the dose was administered,
14 5 the manner in which the dose was administered and
15 6 the relationship between the dose and death?

7

A. I agree, I don't think we
7 can make reasonable estimates based on the tissue
8 concentrations.

9

10 Q. And for all the reservations
11 10 that you have expressed in your report and your
12 11 letter to Dr. Smith?

13

A. That is correct.

14

15 Q. Well then, I want to ask you
16 14 to go please to your case summary which you have
17 15 prepared for the people at the Centers for Disease
18 16 Control.

19

A. Let me locate that.

20

MS. CRONK: That's Tab 23, sir.

21

THE COMMISSIONER: Lombardo are we
22 21 talking about?

23

MR. STRATHY: We are talking about
24 23 Lombardo.

25

THE COMMISSIONER: Yes, all right.

26

MR. STRATHY: Can we turn to what may
27 26 be the third or fourth page of that summary, Doctor,

28

29



1

2 where there is the typewritten comments. The
3 comment that troubles me in view of what you have
4 said about the reservations concerning exhumed
5 tissue is your comment on the likely route, dose,
6 timing of administration where you say - do you have
7 this?

8 A. I am getting it.

9 Q. Okay, I will give you a moment
then.

10 You say:

11 "IV bolus or rapid infusion shortly
12 before death 30 to 60 minutes",
13 and I just really, in view of what you have just told
14 us and all the reservations expressed in your report,
15 your letter to Dr. Smith and so forth, that really
16 that statement is impossible to make based on the
exhumed tissue?

17 A. It is impossible to make
18 solely on the basis of the exhumed tissue, yes.

19 Q. Well then, the only other
20 fact that might come into play was the child's
21 terminal event?

22 A. That is correct, and the
serum potassium elevation bothered me too.

23 Q. All right. But you have told

24

25



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Kauffman, cr.ex.
(Strathy)

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2 us really the terminal event itself, as we have
3 heard in so many other cases, is ambiguous?

4 A. I am not sure what you mean
5 about the ambiguous terminal event.

6

7

8

— — —

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terminal event itself is not inconsistent with digoxin toxicity, or is consistent with digoxin toxicity, but it is also consistent with the child dying in the manner that I have posited to you?

6

A. That is correct.

7

Q. And indeed the child's serum potassium in and of itself is not necessarily indicative of digoxin toxicity as being the cause of death?

11

A. No it is an inconsistent finding.

12

Q. But it is not inconsistent with other physiological findings?

13

A. I don't remember. Well, it is inconsistent with some physiological conditions, yes.

16

Q. It is not inconsistent with the child's underlying physiological state?

18

A. Well I think if you are referring to her condition before her sudden change when she had her arrest --

20

Q. Let's go to that --

21

A. We had better turn to the chart..

22

Q. All right, can you do that please.

24

25



1
2 I2 A. Because I don't remember
3 specifically when that sample was run and it is
4 important.

5 Q. That is what I wanted to ask
6 you.
7

8 A. If we can find --
9

10 Q. I think you should do your
11 thinking to yourself and when you have had a chance
12 to find that --
13

14 MS. CRONK: That is 102.
15

16 MR. STRATHY: 102, thank you.
17

18 A. Did I refer to the description
19 after the terminal event or the laboratory --
20

21 MS. CRONK: The laboratory.
22

23 THE WITNESS: Okay, that is noted
24 at --
25

16 MR. STRATHY: No time.
17

18 A. No time noted on December 23,
19 which was the date of death.
20

21 MR. SHANAHAN: Mr. Commissioner, if
22 it would assist, page 19 Dr. Halpern in doing his
23 summation indicates at line 3:
24

25 "About ten minutes after the arrest
the pH was 7.16..."
26
27 And he goes and he says:
28
29



1

I3

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"The potassium was 7.4 not hemolyzed."

3

4

So it seems to me that Dr. Halpern
is putting a time on that on December 23rd.

5

6

THE WITNESS: So that was obtained
shortly into the arrest.

7

MR. SHANAHAN: Ten minutes into the
arrest.

8

THE WITNESS: Thank you.

9

MR. SHANAHAN: If you can locate
page 19.

11

THE WITNESS: In the chart?

12

MR. SHANAHAN: In these charts that
you might have, Exhibit 78, sir.

13

THE WITNESS: Thank you.

14

MS. CRONK: Doctor, if you turn to
page 41 of the progress notes you will see the
medical resident's notes as to the arrest and that is
where the level is noted.

18

19

MR. STRATHY: Q. All right, would
you read that out, doctor, from the notes.

20

21

A. Okay. This note is timed
December 23 at 0425 is the time of the note. The
note is:

22

23

"Called at 0330 regarding irregular
apex and bradycardia. Baby cyanosed.

24

25



1
I4 2 Cool extremities; weak pulses; heart
3 rate irregular 50-180 with variable
4 QRS patterns. No murmur heard."

5 Q. Just stopping you there, the
6 "no murmur heard" if the shunt was operating properly
7 and was not occluded one would expect to hear a murmur
8 would they not?

9 A. You would expect to hear a
10 murmur. Now because of her arrhythmia her cardiac
11 output had suddenly decreased you might not hear a
12 murmur and still have a patent shunt, so it is
13 ambiguous.

14 Q. All right.

15 A. Then at 3:40:

16 "Vomited - suctioned. 3:45 arrest -
17 ventricular fibrillation massage
18 started.

19 3:48 25 team taking over resuscitation."

20 And at 0400 a blood sample was
21 apparently obtained which would be approximately ten
22 minutes, fifteen minutes into her arrest. The pH was
23 7.16, and the other blood gases were abnormal,
24 consistent with the arrest and her potassium was 7.4
25 at that time.



1
2
3 15 Q. Does the arrest itself result
in changes in potassium chlorides and so forth?

4 A. Yes, and as I pointed out the
5 other day the drop in pH due to the arrest can also
6 account for it, at least in part, not totally.

7 Q. So would you agree that one
8 explanation for that potassium may be the very fact
9 that it was taken after the arrest had begun and as
a result of the arrest having occurred?

10 A. That is correct, that is why
11 I wanted to assure myself as to when it had been
12 obtained.

13 Q. Thank you. Doctor, finally,
14 Allana Miller please. If you could turn to your
15 own report or your letter to Mr. Wiley, at page 5,
16 at the very bottom of the page. You refer to the
17 digoxin concentration in the myocardium of between
18 5 and 7 nanograms per gram, that is tissue preserved
19 in Klotz solution. That would seem to be not simply
low but really very very low tissue levels.

20 A. If I recall correctly those
21 were among the lowest concentrations in fixed tissues
22 of all of the patients.

23 Q. And it is the low level in
24 the tissues of Miller that caused you to posit that

25



I6 2 the administration of digoxin occurred very close to
3 the time, relatively close to the time of death?

4 A. Yes, that is correct. And
5 given the vagaries of those concentrations in
6 attempting to place a time that influenced me to
7 suggest that it could have occurred shortly prior to
her death.

8 Q. And I just wanted to be clear,
9 doctor, would you go so far as to say that in the case
10 of Miller it is possible in view of those low tissue
11 levels that the child received a dose of digoxin at
12 or very near the time of the terminal symptoms, as you
13 call, them developed?

14 A. I think it is possible that
15 she could have received it shortly enough before the
16 time that there would have been minimal tissue
17 distribution.

18 Q. And by shortly enough would you
19 be prepared to accept something in the five to ten
minute range?

20 A. Well at least fifteen minutes.

21 Q. And again that would be on a
22 hypothesis of as little as a single adult vial of
23 digoxin?

24 A. I think that is consistent with



1

17 2 my estimates, yes.

3 MR. STRATHY: Thank you, doctor.

4 Those are all my questions, Mr. Commissioner.

5 THE COMMISSIONER: Yes. Thank you,
6 Mr. Strathy. Mr. Scott.

7 CROSS-EXAMINATION BY MR. SCOTT:

8 Q. Doctor, while we are dealing
9 with it and you have the file at hand, the Miller
10 file at hand, perhaps I can just clean up some
matters that concern me about Miller.

11 First of all this baby was about a
12 year old approximately and I think about 6 kilos on
13 admission, is that right?

14 A. She was eleven months according
15 to my notes, I don't know about her weight.

16 Q. All right.

17 A. Let me look to see what I
18 assumed. I assumed a weight of 6.11 kilos, so I
must have gleaned that from the chart.

19 Q. And the record reveals that
20 Allana Miller had been on digoxin therapy for most if
21 not all of her life, is that your understanding?

22 A. I think that is correct.

23 Q. I am telling you things that I
24 think are correct, and if you want to look it up or

25



1

18 2 disagree with me you tell me.

3 A. I can confirm that. Yes, she
4 had been on maintenance oral digoxin 0.3 mg. twice
5 daily for a number of months.

6 Q. And the chart reveals, and I
7 don't have the page, but at 9:00 p.m. on the day
8 before her death, on the 20th, she received 0.032 mg.
9 orally. Do you want to check that out just to be
sure I have it right.

10 A. Yes, that seems consistent
11 with --

12 Q. It is at page 38 of the chart
13 I think. I am not a doctor and barely a lawyer
14 so I want to be sure that I am reading this right.

15 A. I would agree with your comment
16 you are not a doctor; I wouldn't agree with your
comment that you are not a lawyer.

17 Q. I can tell you there are a number
18 here who will make up for that reservation of yours.

19 Do I read that right that at 9:00 p.m.
20 Allana would have received 0.032 mg. orally?

21 A. At 2100?

22 Q. Yes, you see I am pre-metric,
23 that is nine o'clock.

24 A. Okay, yes.

25



1

19 2 Q. And I think her chart reveals
3 that the terminal events --

4 THE COMMISSIONER: You can't blame
5 the 24-hour clock on metric, can you?

6 MR. SCOTT: Why not we seem to blame
7 everything else on metric.

8 Q. The chart also reveals that
9 her terminal event began some five and a half to
six hours later.

10 A. I believe that is correct.

11 Q. All right.

12 A. At 1:45 a.m. I have in my
notes.

13 Q. Now Mr. Cimbura's readings of
14 the serum levels I think are 69 and 78, or somewhere
15 in that highly elevated level.

16 A. I have on my notes, if they
17 are correct, that the 78 was done at Sick Children's
18 and the 69 was obtained at CPS.

19 Q. All right. But there are those
20 two serum levels obtained?

21 A. That is correct.

22 Q. And there are tissue levels
23 also obtained, do you have those in front of you?

24 A. I have myocardium levels of 5

25



1

110 2 and 7.

3 Q. Have you got a lung level of 4?

4 A. I didn't have in my notes, if
5 you can point me to the report.

6 Q. I think if you look at Mr.
7 Cimbura's document, which is Exhibit 95, do you have
that?

8 A. Yes, if I can find Allana
9 Miller.

10 Q. It is page 5.

11 A. Okay.

12 Q. And that is where you obviously
13 got your 5 and 7 for heart tissue, half-way down the
14 page the right-hand side.

15 A. Yes, I see it now.

16 Q. Then there is a lung tissue
17 isn't there for 4 just below that?

18 A. Yes, that is correct.

19 Q. A level of 4; there is a fluid
20 level of 4 below that.

21 A. That is correct.

22 Q. Then there is a lung fluid
23 level of 5.4.

24 A. That is correct.

25 Q. And those essentially are levels



1
2 Ill with which we have to work in the case of this baby.

3 A. In terms of tissue?

4 Q. Yes.

5 A. Yes.

6 Q. And you have already given us
7 the serum levels?

8 A. That is right.

9 Q. Now I understand from elsewhere
10 in the testimony that a therapeutic level in heart
11 tissue would run the gamut anywhere I think from 49 to
12 900 odd, is that correct?

13 A. In that general range, yes.

14 Q. Yes.

15 A. I should say that those are
16 concentrations which have been measured in people who
17 were thought to have been receiving therapeutic doses
18 and who exhibited no toxicity.

19 Q. Right. So that is the problem
20 we have to work with. Now the thing that caused me
21 trouble with the Baby Miller case is here you have a
22 baby who has been digitalized for most of her life
23 and produces a ~~high~~ ^X tissue level way below any
24 therapeutic level, right?

25 A. Well I will agree that she has
a level in fixed tissues way below the level you would



1

112 2 expect in a digitalized baby.

3 Q. Yes, and I will put it you
4 way below a level you would expect in a baby who
5 had been digitalized some six hours before, or seven
6 hours before.

7 A. She had not been digitalized
8 she received a maintenance dose.

9 Q. Right.

10 A. But that is not the same as
11 being digitalized.

12 Q. I see, I'm sorry. By digital-
13 ized you mean initiating doses, do you?

14 A. I mean she has enough digoxin
15 in her body to produce a pharmacologic effect.

16

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(Scott)

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Q. What I am suggesting to you,
the problem I am having difficulty grappling with,
is here you have a baby who because of her heart
difficulties is on digoxin therapy and has been on
that therapy as far as we know consistently for some
long period of time, or relatively long, and yet
a tissue level shortly after death shows a level
below the normal therapeutic range and substantially
below.

Tissue fixed
in Klok
should fix
many months!

3

Have I stated what we see?

4

A. Well, if we can accept that
number. I think I understand what you are saying.

5

We have a level in tissue that is
quite low. It would be extremely low for fresh
tissue. The problem in talking about it is that
it is fixed tissue. Again it is this problem that
we face with all of them. But, yes, it is a very
low concentration.

6

Q. Leaving aside ---

7

A. And yet she was supposedly
receiving the drug during the month prior to
admission.

8

Q. And leaving aside any murder
case or anything like this, if we knew about that,
just taking Miller in isolation, wouldn't it raise

9

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a question about whether the digoxin therapy was having the desired therapeutic effect because it wasn't getting into the heart in sufficient quantity?

6

7

8

9

A. Well, looking at this, my main question was and still is, whether she was actually getting her medicine before she came in the Hospital. She had a very low serum level when she arrived too.

10

11

12

13

14

15

16

17

18

Q. That, you see, is to raise another spectre and you may be entirely right about that, but what I am suggesting to you is that if you leave out the excitement of the murder case for the moment and just look at what we know about this baby, isn't there a question to be asked about whether digoxin was - assuming she was being administered - was getting to the place it has to be getting in order to do its work? That is, the heart.

19

20

21

22

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24

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A. I really have no precedent at all to assume that. I think the fallacy in this, in the assumptions that are inherent in what you just said is that she was getting her medicine. The most likely probability is that she wasn't getting her medicine at home



1

2 because that is something we see all the time in
3 patients who come in ---

4 Q. Well ---

5 A. - who come in with levels
6 that are not what they should be, and that is
7 consistent with her low level in serum when she
8 arrived at the Hospital, and I suspect that that
is really what was happening.

9 Q. Well, look, let me ask you:
10 it is difficult to answer an irregularity that I
11 present to you by posing another irregularity even
12 though it might be quite possible that the mother
13 didn't do her job by administering the ---

14 A. I think it is highly likely.

15 Q. Well, I know, but it doesn't
16 answer a problem on the case by saying, well, it's
all the mother's fault.

17 Now I ask you to assume - you made
18 the odd assumption in your testimony over the last
19 two days - I ask you to assume that the mother
20 was administering the digoxin as prescribed, and
21 that there was in the Hospital an administration
22 as noted at 9:00 p.m.

23 Now I suggest to you on those two
24 assumptions the level of 4 in the heart post mortem

25



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2 raises a question, doesn't it?

3 A. If you make the assumption
4 that she was getting her medicine and she was
5 eliminating it at the rate that most kids that
6 age would, and if she had serum concentrations that
7 you would expect on her maintenance dose and the
8 maintenance dose was appropriate for her size, you
9 would expect her concentrations to be higher than
10 that. I suspect even in fixed tissue, ~~but~~ let's
11 say that her fresh tissue concentration was 30
12 I can't say that it couldn't be 6 in fixed tissue,
so that is the problem I having.

13 Q. Well, what I am suggesting to
14 you, it is all very well to make assumptions of
15 irregularity. But let's for the moment make an
16 assumption of regularity, that the mother did what
17 she was told to do, that the person who says they
18 administered digoxin at 9 o'clock orally did so
and I suggest to you if that is so this level raises
a question. I put it no higher than that.

19 A. Yes. It is difficult to
20 explain, you are right.

21 Q. Okay. Now what I want to
22 suggest to you is a possibility - I don't put it any
23 higher than that. A possibility is that for some

24

25



1

2 reason that we don't understand having to do with
3 the physiology of this child, the digoxin is not
4 making its way to the heart. Now that is a
5 possibility with which we have to contend, isn't
6 it?

6

7 A. I suppose anything is possible
8 in the universe. It seems so - I mean it is so
9 different than anything that has been described in
10 nature to date with this drug that I find it difficult
11 to believe it as a possibility, but there are a lot
12 of things we don't know so ---

12

Q. Exactly.

13

A. - so I can't say it isn't a
13 possibility. It seems very remote to me.

14

Q. And there are a lot of things that
15 we have learned in the last year aren't there?

16

A. Yes, but none of them would
17 suggest that this possibility would be any more
18 probable.

19

Q. All right. But the problem
20 that you confront then is the serum level which is
21 very high?

21

A. That is correct.

22

Q. And you say that that must
23 be or is probably another dose after 9:00 p.m.,

24

25



1

2 illicit, which has not yet worked its way into the
3 heart, which has not been distributed?

4 A. Yes, that is my hypothesis.

5 Q. What I am asking you is
6 where is the distributed digoxin that was administered
7 at 9 o'clock?

8 A. Well, you are giving me - to
9 answer that, if I answer that with all the assumptions
10 you have given me, then I can't explain it.

11 Q. So that ---

12 A. If I answer it with what
13 I think were the facts as the most probable situation
14 then I can explain it.

15 Q. Let me ask you this: if this
16 child was a normal child and was - I mean if there
17 was no unique feature of her case and she took and
18 reacted and absorbed digoxin normally, what would
19 you expect after an oral administration of digoxin
20 at 9:00 p.m. to find in the heart tissues some six
21 or seven hours later?

22 MR. HUNT: I am sorry, Mr. Commissioner,
23 my friend keeps referring to this as if it is fresh
24 heart tissue, and we started off with fixed.
25 Perhaps we should ---

26 MR. SCOTT: Q. Well, the Doctor can



1

2 answer it either way he wants.

3 A. If your assumption is correct
4 that she was fully digitalized and then we assume
5 that her fresh, her living tissue concentration was
6 something above 45, I wouldn't expect that
7 concentration to change significantly after a
maintenance dose.

8 Q. So it would be what?

9 A. Well, it would be ---

10 Q. What level would you anticipate?

11 A. With the assumption that she
12 had already digitalizing amount of digoxin in her
13 body which is the assumption we started with I
think.

14 Q. Yes.

15 A. And so that would mean based
16 on the literature her myocardial concentration
17 before she got that maintenance dose was something
18 above 45.

19 Q. Yes.

20 A. Given the range we agreed on,
21 then I would not expect a maintenance dose to change
22 whatever her pre-existing myocardial concentration
23 was, change it significantly.

24 Q. It would maintain it?

25



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2

A. It would maintain it.

3

Q. At 45?

4

A. At whatever it was. 45 or

5

whatever it was above that. I am using the range
that we agreed on, 45 to 900 and some.

6

THE COMMISSIONER: I wonder, you
may be asking, but if we take the other assumption,
namely that the mother had not been giving digoxin,
but we still have this dose at 9 o'clock.

7

THE WITNESS: Yes.

8

9

THE COMMISSIONER: And five or six
hours later ---

10

11

THE WITNESS: I think that is the
most likely thing. I think that ---

12

13

MR. SCOTT: Q. Could I interrupt to
ask you why. Do you know the mother?

14

15

16

17

18

19

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A. No, but I know what has been
described over and over in the literature about
medication administration practices by individuals
and parents, and I know what I see every day of the
week when we measure drug levels in people on an out-
patient basis, and I know what I wrote about it a
couple of years ago on drug compliance, so I don't
think this mother would be any different than any
other mother if the kid didn't get her medicine



1

2 part of the time.

3

4 THE COMMISSIONER: Assuming that she
hadn't been getting her medicine.

J

5

THE WITNESS: Okay.

6

7 THE COMMISSIONER: Assuming that the
dose was given at 9 o'clock the night before ---

8

9 THE WITNESS: I think these fixed
3 tissue levels are not inconsistent with that
scenario.

10

11 A single maintenance dose of this
12 size would not - if she had not been getting her
13 medicine, she didn't have very much digoxin in her
14 myocardium to start with and she got this maintenance
15 dose the evening of admission, I would not expect
her myocardial digoxin level to be much higher than
this.

16

17 THE COMMISSIONER: Excuse me, Doctor.
18 Like you, Doctor, and more than you, Doctor, I have
19 trouble distinguishing these children. When did
this child come into the Hospital?

20

21 THE WITNESS: I would have to look
22 at the chart.

23

24 THE COMMISSIONER: What I am really
25 getting at, is this the only ---

MR. SCOTT: Q. She came into the



1

2 Hospital on the 19th and she had a dig. level of
3 .6 on the 19th.

4 A. That apparently was a level
5 drawn shortly after her admission.

6 Q. Yes.

7 A. Is that correct?

8 Q. Yes. I am looking for the
time and I still can't read these things.

9 THE COMMISSIONER: Was this the first ---

10 MR. SCOTT: It is page 88.

11 THE COMMISSIONER: Was this the
12 first that ---

13 MR. SCOTT: It says no time, so it
14 is not much help except that it was on the 19th, and
presumably before 2130.

15 THE COMMISSIONER: But was this the
16 first dose that she had, this digoxin dose at
2100 on the 20th?

17 MR. SCOTT: She was supposed to be
getting digitalized at home.

18 THE COMMISSIONER: Yes. Well, I
19 understand that.

20 MR. SCOTT: But this was the first
21 dose in the Hospital.

22 THE COMMISSIONER: Yes.

23

24

25



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MR. SCOTT: Q. She came into the Hospital, as I understand it, and Doctor, you tell me if I am reading anything wrong, certainly on or before March 19th and she had a dig. level on the 19th, no time, of .6. Have I read that right?

3

A. That is my understanding, yes.

4

Q.

So doesn't that suggest that before she came into the Hospital she had been having some dig.

5

A. I think she had some dig., yes.

Q. Yes.

6

A. I think we have to accept that.

7

Q.

The competing or I shouldn't call them theories or the assumptions - your assumption based on your experience is that the parents may never have been administering or may have overlooked the administration or forgot to do it or done it inefficiently or something of that type?

8

A. Probably missed some doses.

9

Q. Yes.

10

A.

Not all of them but some of them.

11

Q. Against that I take it you

12

have to weigh the fact that when the child came to the Hospital there was a reading of .6 produced?

13

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TORONTO, ONTARIO

Kauffman, cr.ex.
(Scott)

6100

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A. That doesn't really bother
me.

4

Q. It doesn't?

5

A. No.

6

Q. It doesn't show you that the
child has been receiving digoxin at home?

7

A. I am not denying she received
digoxin. I am saying she was not getting all that
she was supposed to receive.

10

Q. I see.

11

A. In fact this is consistent
with that because it is well below what I would
predict if she was getting that maintenance dose
consistently.

14

Q. All right. So I take it
that - what do you say about the possibility that
dig. is not making its way to Allana Miller's heart
as might be anticipated? What do you say about
that possibility? We are talking about possibilities
in this case as you have been from beginning to end.
What do you say about it?

20

A. I say when I hear hoofbeats I
think horses.

22

Q. Well, that doesn't help me with
my possibility. You hear hoofbeats in my possibility?

24

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2 A. I think that ---

3 Q. You have never heard a
4 camel's?

5 A. That is right. Certainly not
6 in Toronto. But I think that that - and I am not
7 being facetious; I really am not - I really honestly
think that is such a remote possibility I can hardly
consider it.

8 Q. All right. But the one
9 thing we know, don't we, is that even on your
10 theory that there was a supplementary dose of
11 digoxin, to use the neutral phrase, some time before
12 death, that digoxin probably did not kill this
13 baby?

14 A. Which digoxin?

15 Q. You posited to explain the
16 serum reading, you posited a dose of digoxin after
17 the oral administration at 9:00 p.m. and before
18 death?

19 A. Right.

20 Q. Now I suggest to you that
21 on the readings if there was such a dose, and there
22 is no record of it, but if there was, and if it
23 explains the serum reading ---

24 A. Which serum reading? Of 70?

25



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2 Q. Of 70.

3 A. Yes.

4 Q. It obviously didn't kill the
5 baby because it didn't get to the heart whereas you
6 have told His Lordship earlier that is where it
7 acts. Or indeed any of the other tissues of which
8 we have knowledge.

9 A. I am not sure I can say that.

10 Q. Well let me tell you: the
11 conundrum of the Miller case is a very high level
12 in the serum and low levels in the tissues?

13 A. Right.

14 Q. Exactly the converse of what
15 one normally would expect?

16 A. Not necessarily.

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Q. All right. Exactly the converse of what one would normally expect if digoxin had only been administered some six hours before?

A. That is correct.

Q. Yes. And to explain that, there are a number of possibilities: the mother wasn't doing the job, that is one that you have advanced to me.

A. You are talking about the low concentration?

Q. Yes. The second possibility is an injection, an unauthorized injection after 9:00 p.m. and before death?

A. Right.

Q. But I take it even on that possibility it cannot be said that that digoxin found its way to the heart. It is clearly in the serum.

A. I don't agree totally with what you have just said. There was digoxin in the heart.

Q. But very little.

A. Well, we don't know that for sure because these were fixed tissues and we just don't know that. The numbers we have are little but we just don't know that it was that little.



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K2

2 Q. All right.

3

A. The other thing we don't know
4 is how much of the digoxin that was in her heart was
5 bound to the specific receptor and was causing some
6 change in cellular activity, we just don't know that.
7 So, I don't think I can agree with you totally that
8 there was no digoxin causing any effect in the heart
at the time of her death.

9

10 Q. Isn't that a possibility to
be considered?

11

12 A. I suppose it is something
again I would have to agree is a possibility. I think
13 it is somewhat unlikely.

14

Q. All right.

15

16 THE COMMISSIONER: Tell me this,
doctor. Supposing you have got no digoxin in your
17 heart at all and you get a dose of digoxin and in the
first instance when it goes into...

18

THE WITNESS: Into the heart?

19

20 THE COMMISSIONER: It goes into the
blood.

21

THE WITNESS: Yes.

22

23 THE COMMISSIONER: And it distributes
itself slowly to the heart. Now, can the very first,
if it is a large dose, can the very first distribution

24

25



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K3 2 bind itself in some way in the heart so as to kill?

3 ' THE WITNESS: In my opinion, yes, it
4 can. Let me explain why. Usually the definitive
5 receptor has a higher affinity for the drug that
6 binds to it than any other binding sites. So that the
7 first molecules that get there are sucked up by the
8 specific receptor or the specific binding site with the
9 highest affinity. Once those are saturated or
10 approaching saturation, probably not totally saturated
11 but approaching saturation, then additional drugs that
12 come in start binding to sites with less affinity.

13 What we are measuring here is total
14 digoxin which includes both specifically bound and
15 non-specifically bound and we are measuring it in
16 fixed tissue where some of the digoxin presumably
17 that is less tightly bound has been leached out into
18 the fluid. So, that is why I can't agree that a dose
19 given as high as postulated would not possibly cause
20 death. Have I answered your question?

21 THE COMMISSIONER: I think you have,
22 I think you have.

23 MR. SCOTT: Q. Well, let's just see
24 if I understand it. The high level in the serum, the
25 low level in the tissue, that's the conundrum that I
present to you, you answer it effectively by saying,



1
2 K4 well, the low level in the tissue is -- do you answer
3 it by saying: For the drug to have killed the baby
4 I would expect if we could see live tissue, a high
5 level in the tissue?

6 A. No, that isn't what I said.
7

8 Q. All right, what do you say?
9

10 A. Well, if you will allow --
11

12 Q. Can I first ask you one
13 question?
14

15 A. Yes.
16

17 Q. What level, if you could take
18 a sample in a baby at the moment of death from its
19 heart, in this baby at the moment of death from heart
20 tissue, what kind of level would you anticipate?
21 Give me a range.
22

23 A. Well, if there had been no --
24 if the baby died instantly, this is quite hypothetical,
25 but if the baby died instantly and you would accept
that that level would be essentially the same as it was
in life, then I think we can use levels that have
been measured at surgery and a baby undergoing surgery
as a guideline for that.

Q. Yes.
21

22 A. And as you have mentioned
23 earlier, those concentrations vary from somewhere
24
25



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K5

2

around 40 to 900 and something.

3 Q. Well, I'm sorry, let me see
4 if I can put it to you this way. We know that there
5 was a reading of .6 when the baby was admitted,
6 serum level, or shortly after admission, we know an
7 oral administration and its volume at 9:00 p.m., we
8 know a post mortem serum level, we know some post
9 mortem tissue levels. All that is the given parapher-
10 nalia with which we have to work. You have suggested,
11 and I accept it, that there was an illicit - I use
12 that word because I can't think what to call it - an
13 illicit administration of digoxin sometime before
14 death, and I forget what time you posited. It
15 doesn't matter for my example.

16

17

A. Well, relatively within an
hour I think I said, I don't remember for sure.

18

19

20

21

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Q. All right. Now, let's assume
that you are right about that. If you had been able
to take a tissue sample at the moment of death, if
you had been able to accurately measure a heart
sample at the moment of death, what range would you
have expected to find there in that scenario?

26

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A. Are you assuming digoxin there
in a therapeutic amount prior to that dose or not?

Q. I am assuming only what we know



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K6 2 that there was a .6 serum reading the previous day,
3 that there was an administration at 9:00 p.m. and that
4 the baby was supposed to have been on digoxin therapy.

5 A. Okay. If I assume that there
6 was a digitalizing amount in the heart prior to this
7 hypothetical dose being given, I would again expect
8 that that -- we are saying, are we, that it was
given shortly before death?

9 Q. Well, at the time you suggest,
10 an hour.

11 A. Yes. I would expect under
12 those conditions for the concentration in the heart
13 to be somewhere in the range we have just described.

14 Q. Namely?

15 A. 40 to 900, you know, this
16 rough range that has been described in babies on
therapeutic doses.

17 Q. And that may have killed the
18 baby?

19 A. It could have, yes.

20 Q. Yes, all right.

21 A. There is such a large overlap
22 that it is hard to say.

23 Q. But that is a scenario that you
24 adopt on the assumptions you have given --

25



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K7

2 A. All right.

3

Q. -- that this dosage an hour
4 before killed the baby?

5

A. Right.

6

Q. All right. So, you would have
7 expected digoxin to be found in that range. Well,
8 the fatal range we know from our reading is 108 to
1240, according to the literature, isn't it?

9

10 A. Those are concentrations that
11 have been measured in tissue in individuals who have
12 been known or thought to have died with digoxin
13 intoxication, yes.

14

Q. Yes. And that is what you
15 are positing about this baby?

16

A. Yes.

17

Q. Yes. So, I suggest to you that
18 you would have expected if you could have done the
19 momentary test I have described with accuracy, a level
20 of 100?

21

A. Well, again, I don't agree
22 with you because I don't think I am communiciating to
23 you my reservation about that. I don't think I have
24 successfully got the concept across.

25

Q. Well, try me again. As I
26 warned you, I am very slow.



1
2 K8 A. One of the problems with me
3 explaining this to you is that we are dealing with a
4 bunch of assumptions here that may or may not be true

5 Q. Exactly.

6 A. -- in terms of what happened
7 before this so-called large dose might have been given.
8 So, I am struggling with trying to keep the assumptions
9 in mind that I really don't believe, but anyway --

10 THE COMMISSIONER: Well, don't do
11 that. I don't think you have to do that. I think
12 what you have to do is just take those that we know,
13 the reading and the dose at 9 o'clock.

14 THE WITNESS: Okay.

15 MR. SCOTT: Q. Have I given you any
16 assumption in the little example that I gave that you
17 don't believe?

18 A. We have to assume what existed
19 before this possible large dose.

20 Q. Yes.

21 A. Because that depends a lot on
22 how I answer your question about possible concentration
23 range.

24 Q. And the question that is there
25 to be debated is whether the mother had properly given
the baby digoxin at home or not?



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K9

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A. Right.

3

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Q. Okay. So, at that point you have opened up two possibilities: That the mother did the job or that the mother didn't do the job?

6

A. Right.

7

Q. Okay. And that produces two answers.

8

A. Could we isolate that now?

9

Q. Yes, by all means.

10

11

A. Let's assume, first of all, that the mother did her job.

12

Q. Yes.

13

14

A. That the baby came in with a digoxin concentration really in her heart of, let's say, 45 or 50, whatever.

15

Q. Yes.

16

17

A. Let's put it at the low end of the so-called therapeutic range.

18

Q. Yes.

19

20

21

22

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25

A. Which is not inconsistent with fixed tissues maybe being 6 or 7, you know, we don't know how much leaches out or breaks down or whatever happens to it. Let's say it was really that and let's say that that was all equilibrated within the heart muscle, there was an equilibrium, that's steady state, . . .



K10

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2 between the specific binding sites and the non-
3 specifically bound or dissolved drug, whatever is
4 existing in there.

5

Q. Right.

6

7 A. And we know that the proportion
8 of the total digoxin that is specifically bound is
9 quite small compared to the total amount in the
tissue.

10

Q. Yes.

11

12 A. So, let's say now she gets a
13 large bolus. If we measure the total concentration,
14 we may not see any significant change; we might see
15 some, we may not. But all I'm suggesting to you is
16 that as that bolus comes to the heart and you
increase momentarily or over a short period of time
the specific binding to cell receptors you can pro-
duce toxicity.

17

Q. All right.

18

19 A. And in the infants that have
20 been treated or in adults too that have been reported
21 over the last couple of years treated with FAB anti-
22 bodies, when the antibodies suck the digoxin out of
23 the tissues, the serum concentration goes up four,
five, sixfold.

24

Q. Well, let me ask you, in that

25



1

K11 2 scenario when the bolus works to the heart and
3 toxicity occurs, what level would you anticipate in
4 the heart?

5 A. That is what I just told you.

6 I think the total concentration may or may not change.

7 Q. From what?

8 A. From the --

9 Q. 49?

10 A. From the background level that
11 existed, whatever it was.

12 Q. And the background level might
13 be anywhere between 49 and 900?

14 A. And if she wasn't taking her
15 medicine, it might be 4.

16 Q. Yes.

17 A. But what I am saying is what
18 we can't measure is what the concentration is at the
19 receptor and that's what could have changed acutely
20 and caused a change in cell function and toxicity.

21 Q. Yes, all right.

22 A. Have I explained what I'm
23 getting at?

24 Q. Well I think I understand.
25 But when I put this conundrum to you that the reading
in the tissue post mortem is only 4 and the reading in



1

K12 2 the other tissues is very low, I take it the problem
3 I haven't confronted is that that is a fixed tissue
4 sample?

5 A. Well, we have taken that into
6 consideration, haven't we?

7 Q. Well, the problem I put to you
8 is that the serum level is very high, the tissue level
9 is very low, the tissue level, if accurate, is pro-
bably not enough to kill, is it, if accurate?

10 A. If it was accurate.

11 Q. Yes, and you told me and I have
12 no doubt you are right --

13 A. Now, wait a minute. No, I
14 don't agree with what you have just said.

15 Q. All right.

16 A. For the reasons I have tried to
17 explain to you.

18 Q. All right. So that this baby
19 could have died with a cardiac level of 4?

20 A. I think it is unlikely but he
21 could certainly die with a myocardial level of 10 or
22 20 or 30 under acute situations with no digoxin having
23 been there or insignificant amounts prior to that
24 bolus.

25 Q. Well, that would be totally



1

K13 2 out of touch with the literature which describes the
3 starting level at 108.

4 A. No.

5 Q. Have I misread that?
I thought that that was one of the first things you
6 told us the other day:

7 "The range of concentrations reported
in cases of fatal poisoning..."

8 This is what Mr. Cimbura said and I thought you
9 agreed with it:

10 "....is 108 to 1,240 nanograms."

11 A. Right.

12 Q. Yes. Are you telling me that
13 a concentration in the heart of as little as 10 can
14 nonetheless produce a fatal poisoning?

15 A. I don't know that it could but
16 I think it is possible. The problem with the ranges
17 that are in the literature is that they are taken
18 at different times under different conditions in
19 different kinds of tissue. You see, that's the
problem.

20 Q. I too accept that it is
21 possible and agree with what you earlier said, that
22 everything is possible. But what I am suggesting to
23 you is that when we have literature that establishes --
24 you know, the literature may be exceptional, what have
25 you, but when we have literature that establishes that



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the fatal range is 108 to 1,240, can we not say that
in the ordinary case it is likely that the range in the
heart of a child who has been killed by digoxin at
the moment of toxicity is probably 108?

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3 that far.

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Q. So you --

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A. I think it is most likely if an individual died of digoxin toxicity and lived for a while, I am talking about hours, after the dose was given so there is some distribution takes place, I think you are right, I accept those numbers.

9

Q. Yes.

10

11

12

A. I don't think we know what the tissue level might be in the kind of situation I am postulating in this case.

13

14

Q. Well, I take it it wouldn't be 4, that would be most unlikely?

15

A. I think that is quite unlikely, yes.

16

17

18

Q. And when I confront you with 4 you very wisely say, well that is a fixed tissue sample and you have to account for leaching.

19

A. It wasn't in the heart.

20

Q. I am sorry, wasn't it?

21

22

23

24

25

A. I think the heart level - I don't think there is a significant difference, I think the heart level was 5, 6 or 7, something like this.

Q. Well I am sorry, I didn't want -



L. 2

1

2 I am sorry, 5 and 7.

3 Q. I don't really think there is
4 a significant difference.

5 MR. STRATHY: I am sorry, Mr. Scott,
6 with your leave, really what it is, it is not even 5 and
7 because those are digoxin and digoxinlike substances.
All Exhibit 95 refers to is traces.

8 MR. SCOTT: Well, we will leave that
9 possibility of digoxinlike substances to be dealt
10 with elsewhere.

11 Q. 5 and 7, you are quite right.
12 What you have explained to me is that you have to
13 take account of the problem of leaching?

14 A. True.

15 Q. Well, if you look at Mr.
16 Cimbura's sheet, page 5, he says:

17 "Fluid surrounding the tissue --".

18 MR. HUNT: I am sorry, what exhibit
19 number is that?

20 MR. SCOTT: I am sorry, 95.

21 MS. CRONK: A.

22 MR. SCOTT: Exhibit 95A.

23 MR. HUNT: Thank you.

24 MR. SCOTT: Q. "Fluid surrounding the
25 tissue, the fluid is reported to be



L. 3

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"Klotz fixative solution. The fluid
was found to contain 4."

4

A. That is correct.

5

6

Q. Well, doesn't that suggest,
even accounting for leaching, the tissue level was not
markedly different than 5 or 7?

7

A. No.

8

Q. What does that suggest to you?

9

A. It suggests that whatever came
out of the heart into that volume of Klotz solution
produced a concentration of 4-1/2 grams per millilitre,
it gives you no quantitative estimate for digoxin at
all.

13

Q. All right. Have I got - just
because I want to be sure I have it to ask others
about, that it is your view that a level of as low as
10 in the heart of Allana Miller could have been the
cause of her death?

18

A. I don't want to get hung up
on a specific number. I think a relatively low number,
and probably a fresh tissue concentration lower than
what we would see in a normal digitalized patient
could have produced lethal toxicity with a sudden
bolus, if that is responsive to your question.

23

24

25

Q. So I take it that the conundrum



L.4

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2 I present simply presents no problems to you at all?

3

A. Which conundrum?

4

Q. The conundrum of high serum
5 levels and low tissue levels?

6

A. No, it is not a major problem
7 to me in trying to put things together. It is a
problem, because the tissue levels are a real problem
8 because of the vagaries inherent in them. If we
9 assume that the tissue levels were quite low, whatever
10 low is and she had a high serum concentration, it
11 doesn't bother me in terms of trying to explain her
12 death and relating it to a digoxin overdose.

13

Q. And when confronted between
14 two possibilities; the possibility of a bolus shortly
15 before death, and the possibility that the mother was
16 not administering the digoxin at home, you selected
the first possibility?

17

A. Now, wait a minute, I didn't
think those possibilities were opposites.

19

Q. Well, are they opposites, or
20 are they not?

21

A. If I had to put the whole
picture together --

22

Q. Yes.

23

A. -- in my own mind, I would

24

25



L. 5

1
2 include both of those I think, if I understand you.
3 I would suggest that the baby was prescribed a
4 maintenance dose at home over those months prior to
5 her admission; that she had not received all of her
6 maintenance doses for whatever reasons, maybe she
7 vomited it, I don't know. But she came into the
8 Hospital with tissue levels that were lower than
9 you would usually expect in a digitalized child. Then
10 she received a maintenance dose, one maintenance
11 dose in the Hospital that evening. I don't think any
12 others prior to her death, because it was held on the
13 20th, and so she didn't receive any subsequent doses,
14 so it was 36 to 48 hours before her death that she
15 received that maintenance dose, and then she could
16 have been given a large --

17 Q. You have included the one she
18 got at 9 o'clock, that is six hours before her death,
19 we know she got that, or it is recorded?

20 A. Now, let us look at the chart,
21 where is that?

22 Q. This is at page 38. She died
23 in the early morning, I think 4 o'clock or something
24 like that, on the 21st, and she got an oral
25 administration at 9 o'clock the previous night.

A. Where is that charted?



L.6

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2

Q. It is at page 38 of the Miller
chart.

3

A. I am looking at page 38.

4

Q. It is at the bottom of the page.

5

A. Yes.

6

Q. Do you see it?

7

A. Yes.

8

Q. Have I read that right?

A. No. Well she didn't, according
to the way I am reading the chart she did not receive
a dose at 0900.

9

Q. 2100 hours, I am sorry, I have
turned that into 9 o'clock.

10

A. I am sorry, yes, 9 o'clock,
9 p.m. As I read it that is the only dose that she
received and that is the one I was referring to.

11

12

Q. That was six and a half hours
before her death?

13

14

A. Yes, my error was I was saying
it was the evening of the date of admission, it was
the following day. She didn't receive any the day
of admission, she received this dose at 9 p.m. on
the 20th, six hours prior to her, approximately six
hours prior to her death, right?

15

16

Q. Yes.

17

18



L. 7

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4

A. So continuing with my scenario,
she received that, and I am assuming it was an
ordered maintenance dose correctly given?

5

Q. Yes.

6

7

8

A. Then my hypothesis to put this
whole thing together is, that then she received a
bolus some time shortly prior to her death which
contributed to her terminal arrhythmia.

9

Q. And is it an essential part
of that scenario that the baby was not properly or
adequately digitalized at home?

10

11

A. No.

12

Q. Or was not receiving --

13

14

15

16

17

A. I don't know if it was

essential but it is the most plausible way I know of
explaining her low concentration in serum when she
was admitted and the low tissue concentration in the
fixed tissues.

18

Q. Yes.

19

A. None of it hangs together real
well.

20

Q. That is what I am getting at.

21

22

23

I mean, we are talking, Doctor, I don't want to
demean the exercise at all, but we are talking a
highly speculative exercise, aren't we?

24

25



L.8

1

2

A.

We are talking a speculative
exercise in her as well as the others.

4

Q.

Oh, yes.

5

A.

And looking for what could be
the most plausible explanation for the whole picture,
I agree with you.

7

Q.

Yes. And what is plausible
one day turns out to be implausible the next day when
a new fact is discovered, we only have to look at
Estrella and your very candid observation that you
moved Estrella from 5 to 2 when a new fact comes to
light?

13

A.

That's right.

14

Q.

And that is the exercise in

which we are engaged as life is imposed on us.

15

Okay, now let me just see where this
hypothesis leads. You have to posit a bolus an hour
before the child's death to explain the serum level?

18

A.

Yes. I had no reason not to
assume the level was there.

20

Q.

What I am suggesting to you

as a possibility, you don't put these things any
higher necessarily, neither do I. What I suggest to
you as a possibility is that the serum level is a
function of the fact that the administered dose at

24

25



L.9

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2 2100 had not moved through the tissues, isn't that
3 a possibility?

4 A. With the vagary of that level,
5 and not knowing whether it was 7 or 70, I think it is
6 even easier to explain it if we say that we didn't
7 have that high level and her tissue level was low
then it all hangs together much better.

8 Q. Yes, but we have two hypotheses
9 which in the state of knowledge can both be held by
10 persons of experience, and one opts for one and one
11 opts for the other, isn't that the situation in which --

12 A. With Estrella you pick your
assumptions and make your choices.

13 Q. Exactly, and it is the same
with Miller, isn't it?

14 A. I would have to look at Miller
15 and compare them.

16 Q. Miller is the one we are
17 talking about.

18 A. All of them have some - have
19 very inadequate data to make a definitive decision, yes.

20 Q. Exactly, and I think you put
21 it as graphically as anybody has in this hearing, you
22 pick your assumptions and you make your choices?

23 A. I think you have to say that,
24 yes.

25



L.10

1

2 Q. Well now, that isn't the end
3 of my problems, I have got some more that I want to
4 confront you about that I don't understand. The first
5 is about half lives.

6 A. Is this in this patient or
7 shall I put the chart --

8 Q. No, this is generally, I can't
9 even get to a patient until I understand this.

10 A. Okay.

11 Q. And as I understand the
12 evidence we have heard so far is, that once you are
13 at a steady state, the half life of digoxin in serum
14 varies between 27.9 hours and 48 hours roughly in Ox.
15 and Griffiths abstract and so on give those figures.

(2)

16 A. Well the variation in infants
17 and patients is even greater than that if you look at
18 all the literature. I mean you can find numbers
19 anywhere from 15 to 80 I think or in those ball parks.

20 THE COMMISSIONER: This is in what we
21 call the beta phase?

22 THE WITNESS: I am assuming you are
23 referring to the elimination half life which would be
24 the beta phase.

25 MR. SCOTT: Q. That is right, yes.
26 But would it be fair to say that we are talking about



L.11

1

2 half lives of what range, in serum?

3 A. Well, as I say the range, the
4 extreme range that I have seen in babies is --

5 Q. In serum.

6 A. In serum 15 to 16 hours to
7 somewhere in the area of 70 hours, I can't remember
exactly the upper range.

8 Q. So that is the range. Then
9 when you come to half life in tissue, heart muscle
10 has been observed at half lives of three and a half
11 days, isn't that so?

12 A. That is correct, that is what
13 I pointed out the other day.

14 Q. I think you also said, perhaps
15 I am wrong, that the right atrial appendage four and
a half days?

16 A. That particular study, the
17 estimated half life in ventrical and atrial appendage
18 were a little different; but the authors pointed out
19 they were not statistically significantly different.

20 Q. Just so we will know where to
21 find it when you go back to Detroit, this is in the
22 Griffiths study.

23 A. Right, I have it, since I
24 brought it with me.

25



L.12

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Q. But you have to leave us some
way to find it.

4

5

6

I take it that the point you made is
that we don't know where on that scale half lives in
other tissues, liver, fat, brain, skin and so on may
fall, am I right?

7

8

A. We have no information one
way or the other.

9

10

Q. We may know next year or two
years down the line but we don't know now, right?

11

A. I would agree with that, yes.

12

13

14

15

16

Q. Now, the next factor I think
I understand from the evidence you gave at the Murphy
inquest is that after the steady state is reached, and
we are speaking in general terms, only 5 per cent of
digoxin by volume is in the serum and 95 per cent is
in the tissues?

17

18

A. I think I said 0.5 per cent
if I recall correctly.

19

20

Q. You are absolutely right, I
read it wrong. The balance, 99.5 per cent is in the
tissues.

21

A. 99.5 per cent, correct.

22

23

Q. Now what I don't understand
is how the half life process works. Let me see, just

24

25



L.13

1

2 see if I can explain the problem. In serum you have
3 a range of anywhere from 15 to 60-70 hours for a half
4 life. So I can understand half life in serum, let us
5 assume a baby with a serum half life of 30 hours, I
6 would understand that if there was digoxin in the
7 serum after 30 hours there is half the volume that
8 there was before; after the next 30 hours there is
9 half of what was left and so on, I have got that right,
haven't I?

10 A. Yes, I think --

11 Q. Okay, now bearing in mind that
12 99 per cent of the volume of digoxin is in the
13 tissues, and the half life in the tissues moves the
14 digoxin from the tissues into the serum, have I got
that right?

15 A. Well, it isn't a half life, it
16 is some sort of equilibrium - obtains.

17 Q. Yes. Well, how do the half
18 lives work in the face of that reality? In other
19 words, you tell us that the half lives in the serum
20 decrease the volume by half depending on what the
21 figure for the half life is, but we know on the other
22 hand that the volume in the serum is increasing at
23 the very same time because of the half life factor
working on the tissues.

24

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2 A. Say that again?

3 Q. Well, if we were dealing only
4 with serum --

5 A. All right.

6 Q. -- I would understand the
7 proposition that after a 30-hour half life you had
8 half the serum volume of digoxin.

9 A. Half the serum concentration.

10 Q. Half the serum concentration
11 in serum.

12 A. All right.

13 Q. So if you had a concentration
14 in serum of 50 after 30 hours you might have a serum
15 concentration of 25?

16 A. Right.

17 Q. Okay. But what is happening at
18 the same time as that is happening is the half life
19 principle is working on the tissues and moving half
20 the volume in the tissues into the serum?

21 A. No.

22 Q. No?

23 A. No.

24 Q. All right. That is my problem.

25 A. Okay.

Q. Because I understood you to say



1

M2 2 to the Judge yesterday that the digoxin in the
3 tissues --

4 MR. HUNT: Sorry, where is the
5 reference to that?

6 MR. SCOTT: It is yesterday.

7 MR. HUNT: That doesn't help me.

8 MR. SCOTT: Weren't you here yester-
day?

9 MR. HUNT: Yes, I was.

10 THE COMMISSIONER: I was but --

11 MR. SCOTT: I'm not going to stop
12 to look it up for Mr. Hunt but I will try to find it
13 for you over lunch.

14 MR. HUNT: If my friend is going to
15 put a suggestion that he said something --

16 MR. SCOTT: Well, it may not --

17 THE COMMISSIONER: It might not be
18 any problem because with this witness at any rate he
will probably put it straight.

19 MR. SCOTT: Well, Mr. Commissioner,
20 just let me record the matter.

21 I recall you yesterday raising with
the witness --

22 THE COMMISSIONER: I recall the
23 question. I can't remember the answer.

24

25



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M3

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MR. SCOTT: -- raising with the
witness the question of whether digoxin given off
by the tissues had to go via the serum before it is
expunged from the body. I don't know if you recall
that, sir --

6

7

8

THE COMMISSIONER: Yes, I certainly
recall the question and I wish I could recall the
answer as well as questions.

9

10

MR. SCOTT: Q. Well, what was your
answer to that problem?

11

12

A. To the question as to whether
it has to go to the serum before it is excreted?

13

Q. Yes.

14

A. Yes, it does have to go into
the serum before it is excreted.

15

16

17

Q. Okay. So do I then have it
right that the digoxin given off by the tissues finds
its way into the serum?

18

A. That is correct.

19

20

21

Q. All right. So that when
digoxin given off let's say by the muscles or the
lungs or something is given off after the first half
life, does it then go into the serum?

22

23

A. The digoxin leaves the
tissues, it goes into the serum.

24

25

Q. Does that process increase the



1

M4 2 volume of digoxin in the serum?

3 A. Will it increase the amount,
4 the --

5 Q. The amount, yes.

6 A. -- the concentration, no,
7 because the digoxin that goes into the serum moves
8 along a concentration gradient to maintain a distribu-
9 tion proportionality.

10 I think I understand what your
11 conceptual problem is, and I need to give you an
12 hour lecture on --

13 Q. No, I don't --

14 A. -- three-compartment pharmac-
15 kinetics to address that.

16 THE COMMISSIONER: Well, I don't know
17 that we have to have that, but what Mr. Scott's
18 concern is that you have a half life where it is
19 getting out of the serum into the tissues but in order
20 to get out into the outside world it has to come
21 back into the serum. Why doesn't that affect the
22 half life of --

23 MR. SCOTT: Q. Why doesn't it affect
24 the volume in the serum?

25 A. Not volume. Don't say volume.

Q. Sorry.



1

M5 2 A. It is the amount in the serum.

3 Q. It does affect the volume,
4 doesn't it?

5 A. No, it doesn't affect the
6 volume of anything.

7 THE COMMISSIONER: Amount is
8 apparently a better word.

9 MR. TOBIAS: Perhaps you should stop
10 while you are ahead, Mr. Scott.

11 MR. SCOTT: I am not sure I am
12 ahead. If I am not ahead it is a bad time to give up.

13 THE WITNESS: I have got a graph of
14 concentrations along time, the log of the concentra-
15 tions, sampling of serum; you can see everything at
16 any concentration of serum with time after an intra-
17 venous dose. It is going to be very high to begin
18 with and transiently it falls very rapidly; it comes
19 around like this; comes down about like this (indicates).

20 Now if we describe this mathematically,
21 we are going to have a series of exponential functions
22 that will describe apparent slope here, apparent slope
23 here, apparent slope here, apparent slope here,
24 apparent slope here and another apparent slope out
25 here. This probably represents nature. When we talk
about half lives we tremendously oversimplify what



M6

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actually exists in nature so we deal with distortion.

2

Now lets say that this is -- I don't want you to get hung up on the time number but I am just trying to make a point. Let's make this 20 days after. So this is 10 days, 15 days, 5 days.

3

4

5

So if somebody does a study of digoxin the way most of the serum kinetics have been done and they measure the half life, the sample, the concentration serum after dose of about 48 to 72 hours. That is out to here, and they measure this slope, and they say that slope is equivalent to 30 hours, half life 30 hours, and when it gets -- when the concentration gets down to this level, their assay doesn't allow them to measure any more so all this literature is published with 30 hour half lives, 20, whatever you said, 20 some to 60 some half life. They measure this slope. We know there is a fast one here, an alpha phase we call it, let's say this is the beta phase.

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We have never looked at this -- deep compartments they are called. If we could measure these extremely low concentrations, we might be able to describe a half life up here of 45 days and I don't know if it exists but conceivably even longer out here.

Now what is actually happening in the



1

M7 2 tissue is when we see this there is a tissue compartment
3 that would reflect if we measured it a 30 hour
4 half life. There is a more tightly bound digoxin
5 that probably includes that exactly that probably
6 has a half life longer than that. But we don't measure
7 it in the serum because we can't. So these people
8 finally tried to do that in serum and because the
9 concentrations are so much higher in serum they can
10 technically measure it and they can describe this
11 longer half life. To me that explains the dilemma
12 that you are dealing with.

13 It is not a problem for me because I
14 think I understand what is happening but it is
15 certainly confusing and I can see how it would be
16 extremely confusing --

17 Q. Well, I am doing my best to
18 look as if I understand, but that is as far as I can
19 go at the moment. But is this your opinion on the
20 question that the volumes -- I know you dislike the
21 word so I will leave it out.

22 A. Well, it is a misnomer, that is
23 why I don't like it.

24 Q. Digoxin being given off by the
25 tissues into the serum does not affect the serum
levels for digoxin?



1

M8 2 A. It does because it affects the
3 rate of decline of the serum level at that moment in
4 time.

5

6 THE COMMISSIONER: What you are
7 really saying is that the half life of the serum takes
8 into consideration the fact that some of the digoxin
9 is coming out of the tissues into the serum?

10

11 THE WITNESS: That is where it comes
12 from, all of it, eventually.

13

14 THE COMMISSIONER: But when you are --

15

16 THE WITNESS: You see you are thinking
17 in absolute quantities instead of rates and rate
18 constants, and I think that is part of your problem.

19

20 MR. SCOTT: Q. Let me put this
21 problem to you: You have baby or an adult that has
22 received digoxin for a period of weeks and has been
23 on a maintenance dose. You have told us that in
24 steady state 99% of the digoxin will be in tissue.
25 You have told us that that digoxin will be given off
in this fashion, half the volume at these intervals.

26

27 A. At a rate -- if you don't give
28 them any more, there is a rate at which it will
29 decline in the tissues.

30

31 Q. Right. And the rate for
32 tissues in those cases where it is known, that is
33 heart, may run three and a half to four days, four and
34

35



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M9 2 a half days?

3 A. These were adult patients
4 undergoing surgery and that is the best information we
5 have.

6 Q. All right. So that if you take
7 a baby who has been on digoxin therapy and the
8 digoxin therapy ceases at the end of let's say Day 10,
9 on Day 11, 12 and 13 digoxin will still be given off
10 into the serum from the tissues on the half life
principle. Is that right?

11 A. I think it is easier -- it
12 might be easier for you if you thought about the
13 rate at which the drug leaves the body rather than
14 getting tied up --

15 Q. Well, let me see if I can just
16 follow one thing. The half life theory means
17 essentially for practical purposes that after five
half lives we are down to minute quantities?

18 A. That is true if you are looking
19 at half life of the drug leaving the body.

20 You see one of the problems is we
21 have introduced an artefact conceptually into
22 pharmacokinetics by having to measure the drug in
23 serum because that is what is available to us.

24 Q. Right.

25



M10

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2 A. And what the pharmacokineticists
3 have done is they have said the way you really ought
4 to be looking at this is the rate at which the drug
5 leaves the body. But the way we are going to describe
6 that is we are going to measure it in serum and we
7 are going to try to relate the serum concentrations
8 to the amount of drug in the body.

9

So your problem is really built
10 around the artefact that has developed conceptually
11 because of the technical limitations that are placed
12 upon it by not being able to sample the drug in
13 tissues with time.

14

Q. Well, I take it that the Ochs
paper tells us that after six days 40% is still in
the body?

15

A. Well, let me comment on the
16 Ochs paper. That is a classical controlled pharmacoco-
17 kinetics single-dose pharmacokinetic study done in
18 normal young adult volunteer males. It is based on
19 serum concentrations and urine collections.

20

What they did, they gave a single
intravenous dose and they collected all the urine,
21 if I remember correctly, for 72 hours. Is that
22 correct?

23

Q. I am not certain.

24

25



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M11 2 MS. CRONK: Put the paper in front
3 of the witness.

4 MR. SCOTT: Q. You see, doctor, the
5 problem which confronts me --

6 MR. HUNT: Mr. Commissioner --

7 THE WITNESS: Well, wait a minute.
This is important, though.

8 MR. SCOTT: Before Mr. Hunt sits
9 down let me tell you the question he wanted to find
10 is at page 5635. Perhaps he will look it up.

11 MR. HUNT: Thank you very much.

12 THE COMMISSIONER: I wonder, doctor,
13 clearly if we are going to get into this Ochs paper
14 we are going to run past the ordinary time for our
break.

15 I would like you -- I don't want to
16 interrupt -- I don't want to go into the Ochs paper
17 now; we can go into it after 2:30, but if there is
18 a question or two you want to ask or would you rather
19 hold all of that and --

20 MR. SCOTT: I would rather come back
earlier if you want to. I don't want you to sit
21 after five o'clock and I don't want you to sit at
22 8:30 in the morning but I don't mind --

23 THE COMMISSIONER: You don't mind if

24

25



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M12 2 I have a short lunch.

3 MR. SCOTT: -- a short lunch.

4 THE COMMISSIONER: I didn't get to
5 this size by having a short lunch!

6 MR. SCOTT: Under my regime I have
7 left plenty of time for elaborate breakfasts and
dinner.

8 THE COMMISSIONER: Well, will it
9 be all right with you if we break now until 2:30?

10 MR. SCOTT: Yes.

11 THE COMMISSIONER: All right.

12 ---- luncheon recess.

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2 ---On resuming.

3 THE COMMISSIONER: Yes, Miss Cronk.

4

MS. CRONK: Just before Mr. Scott

5

continues I am obviously concerned about some
6 scheduling difficulties. Mr. Scott's best estimate,
7 to which he should not be held in any way at the
moment, is an hour; Mr. Ortved a half an hour and
8 Miss Symes is an hour and a half.

9

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I have explained the scheduling
difficulties to Dr. Kauffman. His preference,
subject to your own views, is that we sit even if
there is a reasonable possibility that we will have
to ask him to return at a later date to complete
his evidence, that we do sit tomorrow and accomplish
as much as we possibly can. The difficulty is that,
despite the best and courteous efforts of the
Doctor, it may be next to impossible for him to
come back before Christmas.

My recommendation to you under the
circumstances, sir, is that we plan as we originally
did to sit tomorrow and accomplish as much as we
can but I think there is a very real possibility
the Doctor's evidence will not be completed by
5 o'clock tomorrow night.

THE COMMISSIONER: After that note of



1

2 gloom, Mr. Scott.

3 MR. SCOTT: So, it's all on me, is
4 it?

5 THE COMMISSIONER: It's all your fault,
6 yes.

7 MR. SCOTT: Fine.

8 THE COMMISSIONER: No, I think what
9 we will do is we will carry on and I think we may
10 sit a little on the late side tonight; not a great
deal on the late side but a little, a little.

11 MR. SCOTT: Q. Doctor, before we
12 get into an analysis of the Ochs paper, which I hope
13 I can avoid, let me just see if I can put again
14 the proposition I was trying lamely to make.

15 The half life in serum you put on
16 the basis of the studies we have at about 36 hours.

17 A. That's a mid range of what
18 had been reported, yes.

19 Q. The reported half life in
20 tissue is either three and a half or four and a half
21 days?

22 A. Yes. I should say it this
23 way, I suppose that the kind of data that is, does
24 not have the confidence level that the serum data
25 is simply because, well, for several reasons: one,



1

2 the way it has to be collected because of the nature
3 of the data and also it is the only one, only study
4 where we have a lot of serum studies to compare.

5 Q. So, the confidence level with
6 the serum study half life is better, is that what
7 you are saying?

8 A. I think, simply because we
9 have more samples and we have more studies.

10 Q. Well, I understand that.

11 A. Yes.

12 Q. So that the half life time
13 for tissue may be higher than four and a half days
14 as well as lower. We simply don't know.

15 A. I think when more information
16 is available that's what I would expect. The other
17 thing we have to remember ---

18 Q. Higher?

19 A. No, it is probably going to
20 scatter on either side.

21 Q. Sure.

22 A. I don't know where in the
23 range of this possibility one study lies. The
24 other thing I think we have to remember is that,
25 as you may have pointed out earlier, different
tissues have different affinities for digoxin.



1

2 So, different parts of the slope of this curve in
3 this serum may represent different proportional
4 contributions at different points in time from
5 different tissues.

6 Q. You see, it is just as
7 significant for me to highlight what we know as
8 what we don't know. You have told us that the
9 confidence level that you have in the serum half
10 life and what I am saying to you is that when we
11 come to the tissue half life the one study we have
12 shows three and a half to four and a half days in
13 certain tissues?

14 A. In myocardial tissues.

15 Q. Yes. We don't have any
16 assistance from any studies as to what the half
17 life is in a whole lot of other tissues?

18 A. That is correct.

19 Q. It may be longer, it may
20 be shorter.

21 A. I think that is fair to say.

22 Q. And you have made the point
23 that even with respect to heart tissues the
24 confidence level because the studies are fewer is
25 not as great and we may have longer half lives or
shorter half lives, we simply don't know yet.



1

2 A. I think that is fair to say,
3 yes.

4 Q. And it is not the only field
5 in which we have some ignorance but that is what
6 we have to work with.

7 A. That's right.

8 Q. Now, all I am saying to you
9 is that, bearing in mind that 99 per cent of the
10 digoxin is in tissues, there is at least a sig-
11 nificant possibility that there will be measurable
12 quantities of digoxin in tissues, four and a half,
13 five and a half, six and a half, seven and a half
14 days, perhaps longer, after the last administration?

15 A. It depends on, as you have
16 said, the half life and it depends on whether it
17 is measurable or not, it depends on how much was
there when you began and how sensitive your
analytical method is.

18 Q. And it therefore follows
19 that you are in no position to say, except as a
20 matter of possibilities, that there may be
21 measurable quantities of digoxin, say, 25 days
22 after the last administration, based on the hard
23 knowledge we have - some hypothesis we can all
24 develop - but based on the hard knowledge we have

25



1

2 that's quite possible, isn't it?

3 A. I don't think I would go so
4 far based on what we know now with saying it is quite
5 possible. I think it is possible but somewhat
6 unlikely is the way I would state it.

7 Q. You wouldn't be surprised if
8 a subsequent study showed that?

9 A. If it showed it I could
10 certainly accept it. Based on what I know now,
11 I wouldn't predict it as being a common phenomenon.

12 Q. Well, what I am suggesting
13 to you is, let's be frank, we don't know anything
14 now that makes that more or less probable, do we?

15 A. No, I don't think we have
16 enough information, no.

17 Q. Exactly. Well then, we don't
18 have to be so categorical about it being not
19 likely, we simply don't know. Isn't that fair?

20 A. 25 days?

21 Q. Yes. 20 days, 15 days, 27
22 days, we don't know.

23 A. Well, if we accept the half
24 life of four hours in myocardium.

25 Q. Of four days?

A. Of four days, I am sorry.



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Q. Yes, but you have said that
might be longer too?

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A. It may be, it may be shorter.
That's what we have to work with.

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Q. You see, Doctor.

MS. CRONK: Let him finish.

MR. SCOTT: I beg your pardon?

MR. HUNT: Let him finish.

MS. CRONK: I am sorry.

MR. HUNT: Miss Cronk's comment was
let him finish.

MR. SCOTT: Yes, I am sorry, go ahead,
Doctor.

A. What I was going to say is,

if we accept what we know a half life of
approximately four days and we say that essentially
all the digoxin that was there when you began it
began declining is gone in five half lives, that's
20 days.

So, based on what I know I really
have to use that as my outside number at the present
time. If I learn something different in the
future then I will revise that.

Q. Okay. So, you put 20 days
as your outside number on the basis of what you now

24

25



1

2 know?

3 A. Well, that's saying that there
4 could still be traces present. I don't know if it
5 would be detectable or not, it depends on how much
6 was there to begin with and how sensitive an
7 analytical method was available to look at it and
8 how much tissue you had to extract it from.

9 Q. Now, in the Ochs paper, I
10 don't know whether the Ochs paper is right or wrong,
11 and you are quite right they were dealing with
12 adults, healthy males I think in their twenties
13 and early thirties.

14 THE COMMISSIONER: What's the number of
15 the Ochs paper ?

16 MR. SCOTT: Exhibit 254.

17 Q. You don't need their ages
18 but they seem to run from a young of 25 to an old
19 of 37.

20 A. I would like to look at the
21 paper if you are going to discuss it, please.

22 Q. Sure. I am not going to
23 discuss it but you can certainly look at it. All
24 I am saying to you is that Ochstells us that in
25 that sample group 40 per cent of the digoxin remained
in the body some six days after the administration?



1

2

A. Well, we are going to discuss
it because that isn't what the paper says to me.

4

Q. Oh, I am sorry, I thought it
was. What does the paper say?

5

A. What they apparently did, as
I read the results section is that they did collect
urine for six days after the start of the infusion
and they collected it in 24 hour intervals for six
days and they measured digoxin in the urine by
radioimmunoassay.

11

Q. Yes.

12

A. And they found the cumulative
excretion by six days of digoxin measured by radio-
immunoassay was 60 to 70 per cent of the
administration dose, depending on the dose.

15

Q. Yes.

16

A. That leaves somewhere between
30 to 40 per cent of the dose that they didn't
account for.

18

19

Q. Yes.

20

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A. What they didn't account for
is the quantity of digoxin that was given by that
single dose that was metabolized by the liver which
they didn't measure and came out in both the bile
and the urine.



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Q. Well, how do you know that?

3

A. Because it has been demonstrated
4 in the past that not all digoxin comes out in the
5 urine as unchanged drug, a little bit of it is
6 metabolized and the estimates are anywhere from
7 5 to 30 per cent. So, if you don't measure the
8 metabolites you don't account for the total dose.

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Q. No, but are you saying that
10 the balance of 30 to 40 per cent would have come out
11 in that fashion?

12

A. I am suggesting it well may
13 have, yes.

14

Q. All right.

15

A. And they didn't measure that,
16 so, they couldn't account for that.

17

Q. So, you categorically reject
18 any conclusion of the type I am purporting to draw
19 or that Dr. MacLeod drew from this paper?

20

A. I am not sure what point you
21 are making. I am just commenting on my interpretation
22 of this paper.

23

Q. Do you know Dr. MacLeod?

24

A. Yes, I do.

25

Q. Yes. He did the following
exercise. He applied that finding to children, and



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there may be some question about that, but that's what he did, he extrapolated from this to children and then he concluded that on the basis of that paper there was a possibility that up to 40 per cent of the digoxin would remain after six days. Now, that is a hypothesis that he advanced. He didn't assert that it was categorically the case. Do you categorically reject it?

MR. HUNT: Well, if my friend is going to put Dr. MacLeod's hypothesis to the witness then I think the witness should have the opportunity to read what Dr. MacLeod said and he may add any qualifications he has before he comments on it.

MR. SCOTT: Here's what he says at page 4275.

A. Can I follow with you, please.

Q. Yes.

A. If there is another copy I can just look at that while you read it.

MS. CRONK: Volume?

MR. SCOTT: Volume 64. Well, actually, if you begin at 4274 at line 14 Mr. Lamek is examining.

MR. HUNT: It actually begins at



1

2 4273 I think about line 6.

3 MR. SCOTT: All right, 4273.

4 "A. The point that I wanted to
5 make with this paper..." and he was
6 referring to Ochs.

7 "....was that, once digoxin is
8 administered in a therapeutic dose
9 or in a super-therapeutic dose, it
10 is bound in a variety of tissues and
11 simply will not disappear from those
12 tissues within a predictable time
13 frame. All the times that you have
14 heard in this hearing refer to
15 disappearance from serum or dis-
16 appearance from the plasma space,
17 and that is a different animal than
18 talking about disappearance from
19 tissues.

20 Q. Let us be clear on that, Dr.
21 MacLeod, because I confess it is a
22 matter about which I am totally
23 confused."

24 That is an admission from Mr. Lamek
25 I am going to note.

26 MS. CRONK: Past tense, was.



1

2 MR. SCOTT: All right.

3

4 "No doubt the confusion was mine
5 alone and everyone else understands
6 it. But let me be clear that I under-
7 stand it.

8

9 We have heard about elimination half
10 life and we have been told that that
11 can be a period of anything from 20
12 to 80 hours and, in the course of
13 five of those half lives of whatever
14 length they may be, you will have
15 essentially eliminated whatever it
16 is - 97 per cent or 99 per cent - of
17 the digoxin.

18

19 You are telling us, as I understand
20 it, that that refers only to the
21 elimination of digoxin from the
22 circulatory system?

23

A. That is correct.

24

25 Q. And does not by any means
indicate that digoxin which had been
administered and which is bound to
tissue is also being eliminated at
the same pace, if at all?

26

A. You are correct. That

27



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"inference cannot be made.

2

Q. Okay. Therefore, let us take
a child who is on a regime of
digoxin; if the last prescribed dose
were a week before the time at which
we take a level, we may find nothing
in blood but that would not necessarily
mean that there may not be still
digoxin bound to tissue.

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Would it be pharmacologically active
still?

A. I can't say that but your
expectation would be that there would
be digoxin remaining in tissue a week
after the last dose of digoxin?

Q. And indeed for, I take it,
a possibly very much longer period than
a week.

A. I think it is impossible to say
what the actual duration would be
under which the drug remained in the
tissue. Clearly, there is some
digoxin that is very tightly bound
in tissues, to receptors. There is
other digoxin which is rather loosely



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2 "bound and, presumably, the loosely
3 bound digoxin gradually comes out and
4 appears in the urine. At some point,
5 probably the tightly bound digoxin
6 comes out too, but that might take
7 weeks. Again, this is not something
8 that has been studied, although this
9 paper gives some hint of what is
going on."

10 Now, that was Dr. MacLeod's evidence and I want
11 to ask if he has advanced a perfectly respectable
12 hypothesis in this *ter a incognito* in which we are
concerned?

13

A. I must say I have the greatest
14 respect for Dr. MacLeod but there are a number of
15 things about what we just read that are confusing to
16 me and I can't agree with.

17

I have problems drawing or extra-
18 polating a great deal from the Ochs paper. It is
19 a classical computer pharmacokinetic analysis of
20 serum digoxin levels and urine digoxin excretions
21 in normal adults, at least, that is my first problem,
22 I don't know how safe it is to extrapolate to sick
23 infants because the literature is replete with
24 differences between infants and adults even when

25



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2 they are well, much less when they are sick.

3 Q. And if I might stop you there.

4 I accept what you say and if you have a problem
5 about extrapolating, it might be that the process
6 is longer in infants who are sick than in healthy
7 adults, or it might be that it is shorter.

7

8 A. I just don't know, I can't
9 extrapolate very easily.

9

10 Q. No, exactly, exactly.

10

11 A. Now, my next problem is that
12 the Ochs paper has nothing to do with tissue half
13 lives or tissue levels. I can't draw any conclusions
14 about tissue excretion from that paper. The
15 third problem I have with it is Dr. MacLeod's
16 interpretation that the fact that they only accounted
17 for 60 to 70 per cent of the dose, depending on the
18 dose that was given says that that much is remaining
19 in the body. I don't think that that paper
20 demonstrates that because they haven't accounted for
21 any metabolites or any biliary excretion and we
22 know that a certain amount of digoxin comes out in
23 those forms.

21

22 So, the paper does not substantiate
23 there was still 40 per cent of digoxin remaining in
24 the body at the end of six days. So, that is another

25



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2 point where I disagree with Dr. MacLeod.

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BB 1

2 Q I want to ask you about one of
3 them, and he is engaged as you are, and I take it we
4 are agreed, you are both engaged in a speculative
5 exercise to a large extent at the fringes of scientific
6 knowledge, wouldn't that be fair?

7 A I think that is fair to say
8 and I think it wouldn't be surprising if we
9 disagreed. We also disagree on religion and politics
10 and we are still friends.

11 Q The point I want to make is
12 that this analysis that doctors have been engaged in
13 as a result of what happened at The Sick Children's
14 Hospital, and where you are giving us inestimable
15 assistance, is an analysis that to a very large extent
16 must be hypothetical because of our knowledge, and
17 is at the fringes of scientific information?

18 A Well, that's a part of the
19 problem, and the larger part of the problem is we just
20 don't have enough data on most of these kids.

21 Q And two years from now the
22 situation may be all turned around, based on the kind
23 of research work that has now been taken up and the
24 alacrity with which your profession is beginning to
25 learn things as a result of this focus of attention,
isn't that so?



BB.2

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2 A. It may be.

3 Q. Yes.

4 A. I don't know whether things
5 will turn around or not, I don't know what things we
6 will have two years from now.

7 Q. Exactly.

8 A. I am trying to deal with what
9 information we have now.

10 Q. And you couldn't have predicted
11 two years ago what information you have now?

12 A. That I think is fair to say, yes.

13 Q. Now, the only question about
14 Dr. MacLeod, because Dr. MacLeod would not assert that
15 he was advancing a categorical truth, I mean I know
16 him and I can assert that; but he was saying was that
17 at the fringes of this knowledge it is possible, on
18 page 4275 that at some point probably the tightly
19 bound digoxin comes out too but that might take weeks.

20 A. That is exactly what I was
21 showing you this morning.

22 Q. So that you would accept his
23 hypothesis that the tightly bound digoxin will come
24 out too, but that might take weeks?

25 A. We don't know that it would
take weeks. The best data we have is that it would



BB. 3

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2 take five half lives, or somewhere around four days.
3 I don't know if it is going to take weeks, I just
4 can't respond better than that.

5 THE COMMISSIONER: I am sorry, I find
6 some area of agreement; five times four days.

7 THE WITNESS: That is two to three
8 weeks, yes.

9 THE COMMISSIONER: If that is any
10 comfort to you, Mr. Scott.

11 THE WITNESS: We have to be careful
12 we don't, that we define what we are saying here, that
13 is not that it will start coming out. If you assume
14 a half life of 4 days in 20 days you would have
15 lost virtually 100 per cent of what was in the body
16 when you started.

17 MR. SCOTT: Q. But I take it that only
18 a modest margin of error would be required on that
19 hypothesis to lead you to conclude that at the end of
20 20 days there might still be measurable quantities?
21 Now I know you are going to tell me it is based on
22 how much went in, and I understand that.

23 A. And how well you can measure it.
24 Q. Yes.

25 A. And which tissue you have. It
26 is a long shot, it may be so, I can't say 100 per cent



BB. 4

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2 that it isn't, no, it may be.

3 Q. And I take it again your
4 observation must be like Dr. MacLeod's a function of
5 hypothesis from limited studies and data?

6 A. I think that is largely what
7 we are dealing with here.

8 Q. Yes. Just let me unveil for a
9 moment a personal problem. Lawyers are used to
10 dealing with building blocks they can measure ; doctors
11 I take it are engaged in a scientific inquiry, which
12 is a different exercise.

13 Having said that let's go to Belanger
14 and Lombardo. You spent a good deal of time, I think
15 I understand what you said at the beginning, saying
16 that because of the problem with exhumed tissue you
17 could really not draw much more in the way of a
18 conclusion but that digoxin had been administered to
19 these two babies at some time?

20 A. I think that is true based on
21 the tissue digoxin levels, yes.

(2)

22 Q. Now, with these babies, and
23 with the other babies, you then as I understood it,
24 and the hypothesis, you attempted to give us some
25 kind of time frame after which, or at which the
digoxin may have been administered. Now I call that,

25



BB.5

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2 just because I am used to the grocery store, the "not
3 before date." You understand what I mean and I think
4 you will recall the formula that you explained to us?

5 A. I am not sure I understand
6 what you are referring to.

7 MS. CRONK: Mr. Commissioner, I don't
8 like to interrupt my friend and this may be confusion
9 on my part. I had not thought that the doctor was
10 able to estimate time or route or dose with respect
to these two children.

11 MR. SCOTT: No, he wasn't, and I don't
12 say he did.

13 MS. CRONK: I thought that is exactly
14 what you did say with respect to them.

15 MR. SCOTT: Q. No, I said with respect
16 to all the babies he attended, and indeed I will
17 come to where Miss Cronk asked you to give an estimate
18 with respect to Belanger and Lombardo on the
19 assumption that the readings were in the ball park,
but we will come to that in a minute.

20 A. You mean the tissue concen-
21 trations?

22 Q. Yes. She asked you to do that
23 and I just wanted to get clear that you had some
24 reservations about that exercise in the case of

25



BB.6

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2 Belanger and Lombardo, and I am right about that, am I?

3 A. I think so.

4 Q. But if you are going to get
5 into that exercise with Belanger or Lombardo, trying
6 to find the "not before date", I take it what you
7 really do is you take the level that you get, that
is one of the items with which you begin?

8 A. Whatever concentration data
9 I am provided with, yes.

10 Q. Exactly. You then make an
11 assumption about the dosage and apply what I may call,
12 I hope I am not wrong, the half life principle.

13 A. I am not sure I did that with
14 these two babies.

15 Q. No, I am talking about generally,
not these two babies.

16 A. You are talking generally?

17 Q. Yes.

18 A. Okay.

19 Q. Isn't that what you do, and I
20 know I have highly simplified it.

21 A. Well, if you are talking about
22 tissue concentrations alone, and we believe the
23 concentration in the tissue really reflects - if we
24 assume for the moment that that concentration reflects

25



BB.7

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2 what the actual concentration was in the tissue at the
3 time of death, or during life, then I at least could
4 assume that the patient was either chronically given
5 digoxin, or that they received a dose long enough
6 before death that there was some distribution into
the tissues.

7

8 Q. Perhaps I can go at my problem
9 a little more abstractly without any reference to
any of these cases just to see if I understand it.
10 If you got at the end the data which is the serum
11 levels, or the tissue levels.

12

A. Now which?

13

14 Q. Either one or the other, you
have got a baby who died and you have got let us say
one or both of serum or tissue level, that is the data.
15 The first assumption you make is that that data is
16 reasonably accurate, or is accurate?

17

A. Right.

18

19 Q. Then having got that someone
comes along and says to you, when was that baby given
20 digoxin and in what quantities? Those are the two
questions that essentially the Crown Attorney, Mr.
21 Wiley, asked you to attempt to answer?

22

A. Right.

23

Q. And I take it the way you do

24

25



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BB.8

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2 that is essentially taking other data such as the
3 weight of the baby and so on that you described, and
4 taking the half life principle with respect either to
5 tissues or serum and applying it on the basis of an
6 assumed dosage. Then if the assumed dosage doesn't
7 work out you have to posit a higher dosage or a lower
dosage, isn't that the process that we are --

8

A. Yes. I didn't do it in these
9 particular cases, but I did it obviously in other
10 cases where I had a little more data.

11

Q. Yes.

12

A. I did what I think you are
13 outlining, I looked at the size of the baby and took
14 an arbitrary mid range estimate for the volume of
15 distribution, and a possible elimination rate constant
16 and said what dose could have produced the level in
this range.

17

Q. Well then, I think I understand
18 the process. Then what I want to suggest to you is
19 that with that process by its very nature requires
20 some very fundamental assumptions which you have
outlined?

21

A. Absolutely.

22

Q. And that if any of those
23 assumptions are shown to be wrong, either now or at
24

25



BB.9

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2 some later stage, it upsets the predictability of the
3 accuracy of the result?

4 A. That is right, and you can take
5 one extreme or the other and calculate it and see
6 what your possible extremes could have been.

7 Q. And the assumption that you
8 plug in can eschew the answer one way or the other?

9 A. That is right.

10 Q. For example, if you plug in
11 half lives of 35 hours, or 45 hours, or half lives
12 of 4-1/2 days or 6-1/2 days, you can alter the results?

13 A. Correct.

14 Q. Isn't that so?

15 A. Yes, that's right.

16 Q. And therefore I suggest to
17 you, and this is not to demean the exercise at all,
18 because it is very useful; but I suggest to you that
19 it is in its nature the best we can do perhaps,
20 but it is fraught with risk, wouldn't that be fair?

21 A. I think so.

22 Q. Of mistake?

23 A. It's not an exercise which will
24 give you an exact estimate.

25 Q. And not only that, but having
26 conceded that, it is very difficult to say what the



BB.10

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2 margin of error may be, because you don't know which
3 assumptions may be wrong and the extent to which they
4 may be wrong?

5 A. Only to the extent that you
6 may know what the extremes of reported estimates for
7 those assumptions are.

8 Q. And therefore I take it that
9 you would want the answers you gave to be read subject
10 to the exchange we have now had?

11 A. I made those kind of caveats
12 very clear in my original report.

13 Q. Well I think you did, and I
14 think you made them clear here. The sense I got from
15 listening to my colleagues was that you were some
16 kind of magic man who could predict how much digoxin
17 was given and when. I take it that when your process
18 is understood it has to be read, to be fair to you,
19 with regard to the very substantial assumptions you
20 are obliged to make, and with regard to the prospect
21 of error of which you may quite properly know nothing,
22 isn't that fair?

23 A. I think that is fair, and
24 the best you can do under those circumstances is say
25 that this is my best estimate of what the most likely
possibilities may have been, that's all we can do.



BB.11

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Q. Exactly.

3

A. And it leaves us all in the
same place.

5

Q. Exactly, it is an estimate
about a possibility.

6

A. I think so.

7

Q. Yes. Well now, on Belanger --

8

A. Some possibilities are more
probable than others.

10

Q. Now that is a theological
question and we will leave that for some other day.
You see the trouble I get into is that Miss Cronk
examined you for Mr. Hunt at page 5760, Volume 72,
about Belanger. Well, let's deal with Belanger at
5760.

15

A. May I see a copy of that, please?

16

MR. SCOTT: Yes.

17

MR. TOBIAS: May we have the volume
number, please?

19

MR. SCOTT: Volume 72.

20

MR. TOBIAS: Thank you.

21

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2 MR. SCOTT: Q. Well, maybe it
3 isn't necessary to read it out loud, doctor. If you
4 would like to read from line 20 on page 5760 over to
5 line 17 on 5762, I don't think you need to hear my
6 voice to do that.

7 Have you had an opportunity to read
8 that now, doctor?

9 A. Yes, I have read from line 17
10 on 5760 to line 17 on 5762.

11 Q. Yes. My worry about that
12 exchange between you and Miss Cronk is that that will
13 be used at some stage - I'm sure not by Miss Cronk
14 but by somebody else perhaps to assert that your
15 evidence was that the digoxin in the Belanger baby
16 could not have been administered except within 20
17 days of his death, and I don't have a note of it now
18 but you gave the same kind of answer with respect -
19 a different time frame I think - but the same kind
20 of answer when she asked you that question about
21 Lombardo as well.

22 I just want to be sure I understand.
23 I take it that that answer must be read subject to
24 your overriding observation that because of the
25 problem with exhumed tissues you can't really draw,
nor I believe can anybody else, draw any significant



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CC2 2

conclusions to a level of significant probability?

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A. I didn't expand on this because I wasn't asked several days ago, but I could explain to you a little more why I said what I did and what I meant. If you want me to I can answer you with a yes or no.

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Q. Well, I would like you to first of all answer with a yes or no.

A. And what is the question again?

Q. The question is --

THE COMMISSIONER: And after you

have answered it yes or no then you are entitled to add --

THE WITNESS: Okay.

THE COMMISSIONER: We always say that to witnesses and sometimes they give us their explanation and forget to tell us yes or no.

THE WITNESS: Okay.

MR. SCOTT: Let me present the

problem. We are trying to find out if we can what we can now as a matter of probability.

A. Yes.

Q. There are all kinds of possibilities. We are trying to find out something to that fairly sophisticated level of probability, and I have



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CC3 2 heard your evidence about Belanger and Lombardo that
3 because of the exhumed tissue, the qualifications you
4 impose - what I am really asking: You are not assert-
5 ing in that answer anything on the balance of
6 probabilities, are you? You are simply saying this is
a good guess on my part but nothing more?

7

A. No. What I said, and I will
8 read it to you, is - the question was:

9 "...You will recall that this child
10 from the time of his admission to
11 the Hospital to the time of his
12 death was hospitalized for approxi-
13 mately 35 days. Again given the
14 information that is available to you
15 from the abstract, and having regard
16 to the concentrations that were found
17 in this child, is it possible in your
18 view that traces of digoxin could be
19 found in tissues, and remember again
20 that they are exhumed tissues, from
21 his body if a therapeutic or loading
22 dose of digoxin had been administered
23 to him in error at any time during
24 that 25-day period?"

25

And I said:

26

"I suppose it is possible, but

27



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CC4

2 considering the dose that he would
3 have received under those conditions
4 I think it is highly unlikely that it
5 would be detected as long as 35 days."

6

7 Q. Now, what I am suggesting to
8 you is that you are not asserting that it might --
9 let me put it this way: Do you agree that it might
10 well be detected for 25 days? Detected?

11

12 A. I think it is highly unlikely
13 that it would be detected with the kind of dose we
14 are postulating here at 25 days, and I will illustrate
15 to you why my reservations in a moment when I am
16 finished.

17

18 Q. All right. Illustrate your
19 reservations, please.

20

21 A. Now as you pointed out the
22 major handicap here is having exhumed tissues, so we
23 have numbers that we have to use which we don't have
24 nearly the confidence in as if they were fresh
25 tissues. They are the only numbers we have and they
could be somewhat larger or smaller.

26

27 Q. Could I just interrupt you,
28 doctor? Is this your assertion based on the proposi-
29 tion that the numbers in Belanger were in the ball
30 park?

31

32



Kauffman
cr.ex. (Scott)

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CC5

A. The ball park of fresh tissue?

3

Q. Yes.

4

A. I can't assume that necessarily,
but let me show you what happens to the numbers if we
use what numbers we have.

6

Q. No, but I am saying to you you
have already told us that you can't use with any
assurance the numbers you have.

9

A. But I am doing a lot of things
through these exercises without a lot of assurance.

11

Q. All right. I am not going to
interrupt you because you are certainly entitled to
tell us whatever you want, but what I am going to ask
you to do is I am going to ask you eventually, if you
want to get into this exercise, to take the lowest
measurable quantity of digoxin, .5, and assume that
that is what the reading of exhumed tissue in Belanger
represents.

18

Do you follow me?

19

A. No, I don't.

20

THE COMMISSIONER: The dose that --

21

no.

22

MR. SCOTT: Q. No. If we have an
exhumed reading of a level in Belanger.

23

A. Yes.

24

25



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CC6

2 Q. All right. You have told us
3 that you have not great confidence that that level
4 represents anything actual.

5 THE COMMISSIONER: Other than the
6 fact that there was digoxin at one time in the child.

7 THE WITNESS: That it is there.

8 MR. SCOTT: Q. All right. I am
9 going to ask you, I don't want to inhibit your explana-
10 tion, but I am going to ask you to assume if you want
11 the best case from the accident point of view, that
is assume the lowest measurable level, .5.

12 A. That is in serum.

13 Q. All right. What is the lowest
14 measurable level in tissue?

15 A. I am not sure, but my impres-
16 sion from the paper that was provided to me was that
17 it was not quite that low. It depends to some degree
18 on the quantity of tissue that is available to
extract.

19 Q. Let's take .5 then.

20 A. Let's take .5 as an illustra-
21 tion.

22 Q. Okay.

23 A. And let's say that this 43 in
skeletal muscle was really .5 and some change took

24

25



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CC7 2 place after burial that the apparent level was
3 elevated from .5 to 43.

4 Q. Yes.

5 A. So let us use .5.

6 Q. Yes.

7 A. But we don't --

8 Q. We don't know. That is it.

9 A. Let's leave it at that. Let's
10 say at 35 days he got a dose somehow, a maintenance
11 dose that he shouldn't have received, somehow he got
12 that 35 days before he died.

13 Q. All right.

14 A. That is our assumption.

15 Q. Yes. That is the first
16 assumption we are making.

17 A. Okay. No, that's the second
18 one. We are assuming a digoxin concentration and
19 now we are assuming when he got the dose.

20 Q. Yes, all right.

21 A. So we have got two assumptions.
22 And the maintenance dose, we don't know what size --
23 we don't know whose maintenance dose it was.

24 Q. Right.

25 A. It may have been for a kid who
26 was three times his size or his size.



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CC8

Q. Yes.

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A. And that we really don't know
for sure.

5

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Q. That is really your third
assumption because you have to pick some figure.

7

8

A. Well, a maintenance dose for
this kid would have been 10 micrograms per kilogram.

9

10

Q. No, but this kid wasn't on
digoxin.

11

A. I know, but you have to make an
assumption.

12

13

Q. Exactly, so you have to make
another assumption.

14

A. Absolutely.

15

Q. All right, that is our third
assumption.

16

17

A. What do you want to assume in
terms of a maintenance dose? A kid his size or
bigger or...? It is your choice.

18

19

Q. Let's take a child his size.

20

A. Okay.

21

22

Q. And I take it there that that
is the third assumption in which variables plugged
in can alter the formula?

23

24

A. That is right.

25



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CC9

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Q. Okay.

3

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A. So let's weight it so we have
the best chance of detecting at the --

5

6

Q. Sure, I have a feeling you are
going to show me up so you tell me the assumptions
to make that help me the most.

7

8

A. I am not going to bait any
traps.

9

10

Q. Well you can see I am not, so
you just go right ahead.

11

12

13

A. Okay. So we have a dose, a
maintenance dose that, well, we don't really need to
worry about that. We will look at the dose a little
bit later.

14

15

Q. All right.

16

A. Because we are going to work

backwards.

17

Q. Yes.

18

19

A. So at 35 days, and can we have
a fourth assumption that the tissue half life is
four days?

20

21

Q. We have to have a fourth
assumption, don't we?

22

A. Yes.

23

Q. All right now, why four days?

24

25



1

CC10 2 A. We don't -- I don't know, we
3 can use one and a half days.

4

5 Q. If we pick three days we are
6 going to get a different result? If we pick five
7 days we are going to get a different result?

8

A. Yes; we will.

9

10 Q. If you think there is something
11 magic about 4, I will go with 4.

12

13 A. It is the only number that we
14 have from tissue, and not even tissues we have here.

15

16 Q. Well, if you accept Ochs, of
17 course, you might pick a much larger figure, mightn't
18 you?

19

A. If I accept what?

20

21 Q. If you accept Professor Ochs,
22 you might pick a much larger figure than 4?

23

A. Professor Ochs didn't --

24

Q. But you didn't, so --

25

A. Professor didn't say a thing
about tissue half life. He didn't even allude to
tissue half life.

26

27 Q. No, but he implied that 40%
28 of digoxin might be found in the body after six days.
29 Now you have explained what you think of that.

30

A. Professor Ochs did not say that.

31

32



CC11

1

Q. I don't --

3

A. Professor MacLeod said that
based on Professor Ochs' paper.

5

Q. Well, therefore there is this
chance that if Professor MacLeod is right and you are
wrong we have again made an assumption that is going
to produce a fundamental variance.

8

A. Professor MacLeod knows better.
He forgot that digoxin was metabolized.

10

11

Q. Okay. All right, we will pick
up the figure 4. That is the figure you came up with
first. I just want to get the variables in this
exercise.

13

A. Okay. 4 into 35 is 9.

14

Q. Don't look at me. 8.

15

A. 8?

16

17

Q. No, you want me to say 9
because it is easy. You don't want fractions.

18

A. 8 is fine. 8 half lives.

19

20

Q. I haven't done this kind of
long division since I was in Grade 5, usually standing
at the blackboard.

21

A. 8 half lives.

22

Q. All right.

23

A. You take 2 to the 8th power.

24

25



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Kauffman
cr.ex. (Scott)

6181

1

CC12

Q. Yes..

3

A. I don't have a scientific

4

calculator with me, but it is going to be an enormous
number and if we multiply that times .5 you are
going to get a concentration that is inconceivable at
the beginning of that process.

7

8

Q. Yes. All right. So what do
you conclude from that?

9

10

11

12

13

A. I conclude that I think it is
highly improbable that this infant could have re-
ceived a maintenance dose 35 days prior to his death
and have a tissue concentration of 48 micrograms per
gram.

14

Q. And in the course of that you
have made four assumptions at least.

15

A. That is right.

16

17

Q. And I take it that a variable
in any of those assumptions can significantly alter
your figure?

19

A. Well, let's do it.

20

Q. All right.

21

A. Let's say that the tissue

half life is really --

22

Q. 10.

23

A. 6 -- 10 days?

24

A. Well, okay.

25

A. 10 days, that would be 3½

half lives.



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(Scott)

6182

1

2 So, we are going to take .5 and one
3 half life prior to that it was 1 and another half
4 life, that was 2 and another half life it was 4 and
5 a half of a half life before that is something
greater than 4.

6

7 Q. Well, add it up, I can't
add it up?

8

9 A. Well, no, this is the final
number.

10

Q. I see, right.

11

12 A. If you pick a half life of
13 10, that's one extreme; if you pick a half life
of a day and a half on another extreme well then,
you end up with, again, a tremendous number.

14

Q. So, what is the range?

15

A. I don't know because I

16

17 don't know what the range of half lives in tissue
are.

18

Q. Exactly, okay. And that is
an imponderable?

19

20 A. But I think it is unlikely,
21 and also I think you have to say, at least I have
22 to say that I think it is unlikely that there would
23 be a tenfold change in tissue concentration, increase
24 in tissue concentration due to changes following

25



1

2 burial, but again, we don't have solid information
3 that I could point to to substantiate that, all I
4 can say is I think that is an enormous change.

5

6 Q. But isn't that in the end
7 why in the case of Belanger and Lombardo you say,
8 these figures can't tell me anything really except
9 that there was digoxin present?

10

11 A. That is I think essentially
12 true, yes.

13

14 Q. Because you have so many
15 variables.

16

17 A. The digoxin levels in and of
18 themselves, really, you can't be certain of anything
19 else other than whether it is true, that it was there
20 and it should not have been.

21

22 Q. Yes. Now, therefore, for
23 Belanger and Lombardo, the whole story depends on
24 the existence of digoxin in two babies who were as
25 far as we know not supposed to have any, right?

26

27 A. Well, it's not the whole story
28 but it is a big part of the story.

29

30 Q. Well, it is the story that
31 we are talking about.

32

33 A. It is a very important part
34 of the story.

35

36



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Q. Right. I take it that the

assumption, which is at the foundation of that fact, is that mass spec. has accurately determined the existence of digoxin in those two babies.

A. I can't comment on the mass

spec.

Q. No.

A. But I assume that what is reported as dig. is in fact digoxin.

Q. Yes. But in those two cases if it were demonstrated that the mass spec. results were not reliable as pointing to digoxin, then you would say, look, I can't draw any conclusions about Belanger and Lombardo?

A. I think that would markedly reduce my confidence in any conclusions that I would draw.

Q. It would move them quickly from 4 and 3 on your Attorney General's list down to 1, wouldn't it?

A. Well, I don't know, I can't comment on what I would do. That wasn't the Attorney General's list, that was the CDC list.

Q. I am sorry.

A. I am not sure what effect it



1

2 would have but I would agree with you that it would
3 lower them to some lower rating I anticipate and I
4 would have less confidence in my original conclusions
5 yes.

6

7 Q. Yes. Well, Mr. Cimbura has
8 indicated that he has less than perfect confidence
9 in the mass spec. with respect to Belanger; you were
10 aware of that?

11

12 A. No, I wasn't. I haven't seen
13 his testimony.

14

15 Q. You would take account of that
16 I take it in rating Belanger?

17

18 A. If I knew what was said and
19 had some confidence in that information, I certainly
20 would take it into consideration, yes.

21

22 Q. Well, let's see if I can find
23 it. 1715 in Volume 52 but we can't find Volume 52.

24

25 THE COMMISSIONER: We could of course
take our break now if you want to?

26

27 MR. SCOTT: No. If you would like
28 to.

29

30 THE COMMISSIONER: No, I don't
31 particularly want to.

32

33 MR. SCOTT: Well, I can't find it and
34 that's my fault. But I take it if Mr. Cimbura had

35

36



1

2 less than 100 per cent -- at page 1713 with respect
3 to the Belanger mass spec. Mr. Cimbura says this:

4 "That's right, there were again two
5 different tests, two separate tests
6 done. The result of the first test
7 was negative with a notation by the
8 mass spectrometrist that the extract
9 was very impure. Following that we
10 have attempted to purify more of the
11 extract by subjecting it to successive
12 HPLC purification and another test was
13 conducted by GC mass spec. The result
14 worded by the mass spectrometrist
15 were..."

16 And he is reading obviously from a form.

17 "....'may be present', and even after
18 this extensive purification the extract
19 was still not an ideal extract for
20 mass spectrometry and after discussion
21 with the mass spectrometrist and my
22 review of all of the results I have
23 reached a conclusion that both results
24 were inconclusive."

25 Now, I take it that if his view is that
the results in Belanger were inconclusive for



1

2 digoxin ---

3 MR. HUNT: I am sorry, it was only
4 the mass spec. results?

5 MR. SCOTT: Yes, that's right, that
6 they were inconclusive for digoxin, would that have
any impact on your views?

7

8 A. Not just the information you
9 have given me. You know, mass spectrometry, as
10 wonderful as it is, isn't perfect either. With a
11 very complex matrix like tissue it isn't terribly
12 surprising that they might have difficulty getting
13 enough material out and isolate it enough that they
14 could produce a good mass spectrum to get a
15 definitive mass spectrum. It isn't uncommon in a
16 situation like that for the mass spectrometry not
17 to be terribly sensitive when they are trying to
18 document the presence of the substance.

19

20 So, based on that information alone
21 that you just gave me, I'm not sure that I would
22 change anything one way or the other at that point.

23

24 Q. Well, you begin with the
25 proposition that there is digoxin present and that
is because what you have been told by Mr. Cimbura
and others?

26

27 A. No. If the only thing that I

28

29



1

2 was told was that they took some tissue and they
3 did an extraction and they injected it on the GC
4 mass spec. and one time they saw a bunch of garbage
5 and the second time they saw a mass spectrum that
6 was compatible but the quality wasn't good enough
7 to be sure of digoxin, I would suspect that there
8 was digoxin there and then if it was important to
9 know, try to do some additional things to try to
confirm it one way or the other.

10 Q. Well, it is important to know
11 here.

12 A. Yes, in this case it is very
13 important.

14 Q. And if the mass spectrometry
15 tests are conclusive, what else do you want to know
16 before you make your assumption that there was
digoxin in the case of the Belanger baby?

17 A. If the mass spec. was definitive
18 in demonstrating the presence of mass spectrum that
19 was digoxin, then that would give me additional
20 confidence along with the immunoassay and the HPLC
21 radioimmunoassay that was there. If the mass spec.
22 was negative, and I'm not a mass spectrometrist,
23 but if the mass spec. was negative then I would
have to be assured that there was a reasonable

24

25



1

2 chance that if it was there they would have been
3 able to produce a spectrum on it.

4 Q. In other words, you would
5 have to be satisfied that for some reason the mass
6 spectrometry failed to produce it for some reason
7 that is legitimate and understandable and consistent
with the presence of digoxin?

8 A. I think if I understand what
9 you are saying I agree with you.

10 Q. Yes.

11 A. You see, in a very complex
12 dirty matrix like tissue a substance could be there
13 and you wouldn't be able to produce a clean enough
14 spectrum to be sure you saw it. If you put the
15 same amount of digoxin in a pure solution and ran
16 the mass spectrum you could produce a nice clean
17 spectrum. That's just a technical problem that
tissue presents.

18 Q. Well, if you were told that
19 in the cases of Belanger and Lombardo the mass
20 spectrometry that was done did not, to a significant
21 degree, illustrate the presence of digoxin in the
22 body, in the exhumed tissues of those two babies,
23 would that lead you to qualify your assumption in
this case?

24

25



1

A. Yes, I think you have given
me a hypothetical question and I will give you a
hypothetical answer.

2

Q. Yes.

3

A. If I was assured that mass
spectrometry had failed to demonstrate the presence
of digoxin in the tissues I would have a greatly
decreased confidence that it was there.

4

Q. Yes. Can you tell me, maybe
it is just an unfair question, what would that do
to your CDC list where you got them at 4 and 3
respectively?

5

A. I would have to look at it but
I suspect, answering you without a great deal of
forethought, that if my assessment of the highest
probability was that there was no digoxin in their
tissues, they would probably be reduced from to a
2 or a 1.

6

Q. Thank you.

7

A. Depending on their clinical
status. You see, I was asked to look at the paper
from a pharmacological point of view.

8

Q. Yes, I understand.

9

A. And when digoxin was not
documented to be present, I did not go on to

10

11



(Scott)

1

2 secondary considerations to a great extent in looking
3 at clinical course and so forth because the
4 cardiologists were doing that.

5

Q. Yes. Well now, let me just
5 go to one or two other areas where my understanding is
6 feeble.

7

The first one I want to deal with is
8 Baby Pacsai. I just have one sort of layman's problem
9 about this baby. We know that this child was very
10 ill at both St. Joseph's Hospital and the McMaster
11 Medical Centre before the baby even came to Toronto,
12 I mean, that is apparent, isn't it. And we know for
13 example that at McMaster, if not at St. Joseph's
14 the serum potassium was over 7 and there was profound
acidosis.

15

A. That's correct.

16

Q. Can I conclude therefore that
17 at McMaster the baby was seriously sick?

18

A. That was my impression, yes.

19

Q. Yes. Indeed, I think if you
look at the chart the baby perhaps almost died at
20 McMaster?

21

A. I think that is apparent, yes.

22

Q. And then the baby was transferred
23 to the Hospital for Sick Children and the chart says,
24

25



1

2 I don't know the page number but I think it is
3 generally - you might not disagree with this -
4 the baby became progressively lethargic, bradycardic
5 and limp and shortly before death had a potassium
6 level again of over 7, 7.7. Is that the way you
have read the chart?

7

8 A. No, I don't think that is
9 all the information that is in the chart. I should
be looking at the chart while you are going over it
10 so I refresh my memory.

11

MR. HUNT: Exhibit 106.

12

MR. SCOTT: I think if you look at
page 63 of the chart.

13

A. 63?

14

Q. Yes. Someone has suggested
page 65.

16

Have I summarized the case reasonably
17 accurately?

18

A. You are looking at page 63.

19

Q. Through 65.

20

A. Oh, through, okay, I am
sorry, I didn't go on.

21

22

23

- - - -

24

25



DM.jc
EE

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2

Q. "After the child was admitted to The Hospital for Sick Children he became progressively lethargic, bradycardic and limp and shortly before death had a potassium serum level of 7.7."

3

4

5

6

7

8

A. That wasn't exactly my understanding of the Hospital course, no.

9

Q. Well, if you look at page 65 for example, half way down the page:

10

11

12

"He was lethargic and limp ... ",

this is the nurse's note.

13

14

15

16

17

18

19

20

21

22

23

24

25

A. That was at the point that he suddenly changed?

Q. Yes.

A. The second day, is it the second day of his hospitalization?

Q. Yes.

A. And remember he was admitted on the 10th or 11th.

MR. OLAH: He was admitted on the 11th at about 3:57, Doctor.

THE WITNESS: In the morning?

MR. OLAH: 3:57 in the afternoon.

THE WITNESS: In the afternoon. Okay,



Kauffman, cr.ex.
(Scott)

EE. 2

1

2 so this is about 12 - if I am looking at the right
3 note it is 3:45 to 6 o'clock, note on March 12th?

4 MR. SCOTT: Q. Yes. Can you find his
5 potassium level just before death?

6 A. So that was about --

7 THE COMMISSIONER: Hold on, Mr.

8 Shinehoft has something to say. Yes, Mr. Shinehoft?

9 MR. SHINEHOFT: I believe Mr. Scott
10 indicated that this baby's potassium level at McMaster
11 University was in the 7 range. I was wondering if
12 Mr. Scott might point out to me where in the chart
13 it indicates that?

14 MR. SCOTT: Well, the chart doesn't
15 indicate it, but Dr. Bain's report; the chart is
16 The Hospital for Sick Children chart, but Dr. Bain's
17 report at page No. 27 - I'm sorry, it is at page 33 of
18 the chart if you want it, the bottom of the page.

19 MR. SHINEHOFT: I have the records
20 from McMaster University and I would be happy to show
21 my friend.

22 MR. SCOTT: It is at page 33 of
23 The Hospital for Sick Children chart, two-thirds of
24 the way down the page.

25 THE COMMISSIONER: Page 33, mine is



Kauffman, cr.ex.
(Scott)

EE. 3

1

2 St. Joseph's Hospital.

3 MR. SHINEHOFT; Yes, that is correct,
4 Mr. Commissioner. I have the potassium levels from
5 Chedoke-McMaster and I would be happy to show Mr. Scott
6 as well as the doctor.

7 MR. SCOTT: The point, the only point
8 I need for this series of questions is that I take it
9 before the child came to Sick Kids he had had a
10 potassium serum level of 7.4, I can demonstrate that
11 by looking at page 33.

12 MR. SHINEHOFT: But you know, that is
13 not the entire picture, Mr. Commissioner, with all
14 due respect.

15 MR. SCOTT: Well, my friend can
16 examine further, I mean, his time will come.

17 MR. SHINEHOFT: If he is going to put
18 the proposition to him I think he should put the
19 proposition to him fairly. I think he should review
20 first of all potassium levels at St. Joseph's
21 Hospital, and his potassium level at the Chedoke-
22 McMaster Hospital, so that the doctor has a true
23 picture of what exactly those levels were before his
24 admission to The Hospital for Sick Children. I think
25 that is only fair, and I happen to have this.

MR. SCOTT: My friend can ask questions

24

25



Kauffman, cr.ex.
(Scott)

EE. 4

1

2 I don't have that information.

3 MR. SHINEHOFT: If you would sit down
4 until I am finished perhaps the Commissioner can
5 perhaps make a ruling. I have these papers here, I
6 have the chart, and I am prepared to show my friend
7 Mr. Scott, and yourself, Mr. Commissioner, and the
8 doctor, so that we have an accurate picture of
9 exactly what happened before this --

10 THE COMMISSIONER: That is true, Mr.
11 Shinehoft, and we don't pay too much attention to the
12 rules of the game. The rules are these, that
13 ordinarily if this were a court of some kind of
14 justice, if this is in evidence before us and if
15 Mr. Scott is putting a question to the witness and
16 putting it inaccurately, then you would have a perfect
17 right to stand up and say it is not done properly, let
18 us put it properly and let us do it. If you have some
19 additional evidence that we haven't had you can't
expect Mr. Scott at this point to be able to rely
upon it.

20 MR. SHINEHOFT: With all due respect,
21 Mr. Commissioner, I referred to it when I examined
22 Dr. Bain and I referred specifically to it.

23 THE COMMISSIONER: Has it been put in
24 in evidence?

25



EE.5

1

2

MR. SHINEHOFT: No, that was --

3

4

THE COMMISSIONER: Then you will have
to do that when it comes your turn to destroy everything
that Mr. Scott has established.

5

6

7

MR. SHINEHOFT: I am not trying to
destroy Mr. Scott, I am just asking Mr. Scott to
present the entire picture.

8

9

MR. SCOTT: If this is the way you are
helping me I can certainly do with it.

10

11

12

13

14

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THE COMMISSIONER: Look, you carry on,
we don't seem to have had that evidence yet so you
don't need to concern yourself with it.

MR. SCOTT: Q. If you look at page 33 -

A. I am handicapped because my
page 33 is unreadable.

Q. Well, mine is pretty unreadable
too.

THE COMMISSIONER: Mine is a little
better if you want to have it.

MR. SCOTT: Q. This is for St. Joseph's
Hospital, and the solicitor for the McMaster Hospital
is a little upset that I haven't referred to it. Does
that not show a potassium level on that page of 7.4?

A. I see K 7.4 and I can't read
anything else around it.



Kauffman, cr.ex.
(Scott)

EE. 6

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THE COMMISSIONER: Up above seems to

be NAL31.

4

THE WITNESS: Was this at --

5

6

7

8

MR. SCOTT: Q. Well, what I am trying to establish and maybe Miss Cronk can help us, is whether there was, before the baby came to Sick Children's a potassium reading of 7.4, I thought that was what page 33 said. Now your chance has come.

9

THE COMMISSIONER: Yes.

10

11

12

MR. SHINEHOFT: I may be able to help you, Mr. Commissioner, I happen to have a legible copy of --

13

THE COMMISSIONER: Page 33?

14

MR. SHINEHOFT: Yes, I do.

15

THE COMMISSIONER: Mine is legible too, I see NAL31, K7.4 and underneath that 96.

16

MR. SHINEHOFT: That is correct.

17

THE COMMISSIONER: I don't know what

18

96 stands for.

19

THE WITNESS: I think that is the chloride concentration.

20

THE COMMISSIONER: All right, chloride, oh yes.

22

MR. SCOTT: Counsel for the parents has agreed that as at that date the baby had, I gather

23

25



Kauffman, cr.ex.
(Scott)

EE.7

1

2 at St. Joseph's Hospital, a potassium level of 7.4.

3 MR. SHINEHOFT: Let me show the doctor,
4 there is a K --

5 MR. SCOTT: I am ahead of even you,
6 I know what the "K" means.

7 MR. SHINEHOFT: Doctor, I think this
is what my friend is referring to.

8 THE WITNESS: Yes, this is a readable
9 copy.

10 MR. SHINEHOFT: You can perhaps use it.

11 THE WITNESS: Thank you.

12 THE COMMISSIONER: Now, Mr. Scott, do
13 you want to get on with whatever that question was?

14 MR. SCOTT: Q. The point very simply,
15 Doctor, is this; that before the baby came to Sick Kids
16 it is apparent that it had a potassium level elevated
17 at 7.4; before death it had a potassium level of 7.7.
18 The baby was very sick. Those three facts we seem
19 to know. Are you with me so far?

20 A. Those facts are very incomplete
21 but technically they are correct.

22 Q. Yes, all right. And your
23 testimony, and I don't have the page for Mr. Hunt but
I will try to get it later on, suggested to me at
least that the high potassium was indicative of toxicity?

24

25



EE. 8

1

2 A. Which one?

3 Q. The 7.7.

4 A. The latter one?

5 Q. Yes.

6 A. I think that is a likely
possibility.

7 Q. All right. Now, how do you
8 explain - let me ask you this, why is the 7.4 at
9 St. Joseph's not indicative of digoxin toxicity?

10 MS. CRONK: Well, now, sir, I am going
11 to be on my feet. The point has been twice made that
12 the witness has not had a chance to review those
13 documents from St. Joseph's. My friend Mr. Shinehoff
14 tried to put the ones from McMaster to him. Surely
15 he is not asked to answer that question, and in all
16 fairness to him he should be given an opportunity to
17 read the entire piece of paper.

18 MR. SCOTT: Sure, he can take all his
time.

19 Q. Do you understand the problem
20 I have?

21 A. I am not sure what your problem
22 is. My problem is I can't interpret potassium readings
23 in isolation without any other information.

24 Q. My problem is that one of the
25



EE. 9

1

2 things you said was that the potassium level of 7.7
3 was indicative in this baby of digoxin toxicity. I
4 accept that. What I want to ask you is, is the 7.4
5 indicative of digoxin toxicity, and if not, is it
6 possible that there is something going on here that
7 is not connected with digoxin that produces an
elevated potassium level?

8

A. I can't comment on the first
9 elevated potassium until I look and see what the
10 surrounding circumstances were. Because as I pointed
11 out the other day a number of things can cause an
12 elevated serum potassium concentration. I really
13 can't respond to your question until I look and see
14 what was going on when the first potassium was drawn.

14

Q. And I take it we haven't got
15 enough material to enable you to do that?

16

A. We may if I have a look at
17 this, I don't know.

18

THE COMMISSIONER: I think Mr.
19 Shinehoft was up first.

20

MR. SHINEHOFT: With the greatest of
21 respect, Mr. Commissioner, I don't think that is the
evidence that the doctor gave.

22

THE COMMISSIONER: What evidence that
23 he gave?

24

25



Kauffman, cr.ex.
(Scott)

EE.10

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4

MR. SHINEHOFT: The fact that the elevated potassium was necessarily indicative of digoxin toxicity.

5

6

THE COMMISSIONER: That is what he said, he said it might be indicative.

7

8

MR. SHINEHOFT: I would refer Mr. Commissioner to page 5796 at line 7, I believe it is yesterday's evidence where the doctor says:

9

10

11

12

"I think we have to remember that

hypokalemia is not a consistent finding in digoxin intoxication, it may or may not occur."

13

14

THE COMMISSIONER: I don't see that at all.

15

16

17

MR. SCOTT: Mr. Commissioner, it is almost time for the break, and before I get any more help from my colleagues at the bar perhaps I can just outline what the problem is.

18

THE COMMISSIONER: Yes.

19

20

MR. SCOTT: The problem is that this baby had an elevated potassium level and died.

21

THE COMMISSIONER: Right.

22

23

24

25

MR. SCOTT: That was taken to be some evidence of digoxin toxicity. The additional fact is that in an entirely different hospital this baby



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2 had an elevated potassium level and almost died.

3 THE COMMISSIONER: Yes.

4 MR. SCOTT: What is that evidence of?

5 THE COMMISSIONER: Let us now take the
6 break and I think we will give the witness time to
7 consider all pieces of paper that everybody wants to
8 hand to him in the meantime. I think I mentioned
9 this to you before, we always managed to ruin a
witness' break.

10 THE WITNESS: Yes.

11 THE COMMISSIONER: But you understand
12 what Mr. Scott's problem is?

13 THE WITNESS: I think so.

14 THE COMMISSIONER: Do you want to
15 answer it now or do you want to wait and look at --

16 MR. SCOTT: Do you want to take the
break?

17 THE WITNESS: I think I could answer it
18 but I need to be sure I am straight on the facts of
19 when the first one was taken, what intervened between
20 and what existed when the second one that you are
referring to was taken.

21 THE COMMISSIONER: Yes. We will take
22 15 minutes and you can look into that.

23 THE WITNESS: Okay.

24 --- Short recess.

25



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1dec83 2 --- on resuming.

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3 THE WITNESS: The question I am
4 responding to is why on the 7th of March 1981 when
5 Kevin Pacsai presented to St. Joseph's Hospital at
6 Hamilton with a potassium of 7.4 not considered
7 digoxin poisoning and why it was consistent with
8 digoxin poisoning at a later date at the time of
his death.

9 Is that a fair statement of the
10 question?

11 THE COMMISSIONER: Yes, that is right,
12 as I understand it. Is that not your question? 7.4 --

13 THE WITNESS: 7.4 on the 7th.

14 THE COMMISSIONER: And 7.7 --

15 THE WITNESS: On the 12th when he
died it was 7.7.

16 MR. SCOTT: Q. The question I am
17 asking is really this: The baby in St. Joseph's
18 had an elevated potassium level and I think almost
19 died. The baby had an elevated potassium level at
Sick Kids and did die.

20 Is there something about that baby
21 or must digoxin be the intervening factor?

22 A. Well --

23 Q. I mean if the baby had died at
24
25



1

FF2 2 St. Joseph's Hospital with a potassium level of 7.4,
3 there perhaps would have been no suggestion of
4 digoxin toxicity. The baby did die at Sick Kids
5 with a potassium level of 7.7 and some people say the
6 baby was poisoned.

6

7

Now can you resolve that dilemma for
me?

8

A. I think so.

9

Q. Thank you.

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A. The conditions at the time the potassium was obtained on the two occasions were quite different. And I think this explains -- it affects the interpretation of the potassium concentration in serum.

As I read the chart when the baby

arrived at St. Joseph's Hospital he was, as you said, almost dead. He was cyanotic. He had a heart rate in the neighbourhood of 240. He was barely breathing. His temperature was subnormal. His blood sugar was very low and they immediately drew blood gases - his pH was 6.97 and among the other laboratory studies that were obtained he had electrolytes done and potassium was 7.4.

The chart suggests to me that these

were all done within a fairly short period of time so



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that probably all that information represents the same condition of the infant at that moment.

4

5

So then therapy was started -- well, let me stop there.

6

7

8

9

So there are at least three very good explanations for the high potassium at that point. One is that he was severely acidotic, and it is well known that severe acidosis increases serum potassium, and I covered that previously.

10

11

12

He was hypoglycemic. That also is consistent with high potassium concentrations.

And he was hypoxic. His oxygen saturation was 66%.

13

14

So there are very good explanations at that moment in time for his high potassium.

15

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17

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Then over the next few hours he responded to therapy. His pH gradually came up and his blood gases became normal and his potassium returned to normal and he was transferred to I believe McMaster.

19

20

21

At McMaster he had a whole series of normal potassium concentrations determined, as well as blood gases.

22

23

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He was subsequently transferred to Sick Children's Hospital, and his first potassium - and now I need to turn to the child's chart if you will



1
FF4 2 indulge me for a moment.

3 I don't know how these charts are
4 put together.

5 THE COMMISSIONER: I don't either,
6 and we have never understood that.

7 MR. SCOTT: Commission staff will
8 answer to that.

9 A. Okay. He arrived at six -- he
10 arrived on the afternoon of March 11th. He I think
11 is described as being stable at that time with normal
12 respiration, normal ekg and normal heart rate, normal
13 blood pressure and so forth. His blood gases reported
14 at 1615 on March 11 were a pH of 7.31 which is okay.
15 I don't have a blood sugar I don't believe, but there
16 is no indication from the chart -- yes, I do. Well,
17 not at that time we don't.

18 His potassium was 3.9 at 1745 on
19 March 11, which is normal. And that I believe was
20 12 to 13 hours prior to his death, his arrest.

21 Then right about the time that his
22 condition suddenly changed he had blood gases obtained
23 probably because he had suddenly changed. His pH was
24 7.47. The oxygen was 161.. Those are both normal.
25 The oxygen was a little high but he was receiving
some additional oxygen in the air he was breathing.



1

FF5 2 At that time, well, an hour and a half
3 later, the potassium is 9. And we know that that was
4 slightly hemolyzed so it was something less than 9.
5 It was repeated at 7:20 and it was 7.7, so we can
6 know that it was somewhat less than 9 an hour before
7 that, or fifty minutes before that, and 7.7 at that
time.

8 So what I have at St.Joseph's is a
9 baby who had been sick for a week to ten days before
10 that. Had in fact been seen prior to that emergency
11 room visit. Had continued to do poorly. Showed up
12 on death's doorstep severely acidotic, hypoglycemic
13 and hypoxic and it is not surprising his potassium
14 was 7.4 at that point. It was in my mind totally
explained.

15 At the time that his potassium was
16 7.7 he had been demonstrated to have normal potassiums
17 prior to that with normal renal function and a normal
18 pH and a normal oxygen status and a normal blood
19 sugar of 82.

20 So I don't have the kind of explana-
21 tions for the second level that I had for the first
22 level, and that is essentially within the digoxin data
23 that was presented in the description of his terminal
event.

24

25



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FF6 2 Q. That wouldn't normally drive
3 us to poisoning, would it, as a cause? Or would it,
4 in the Hospital?

5 A. I think I said it was consistent
6 with that. It could have been due to other things.

7 Q. What I would like to suggest
8 to you is the history reveals, as a hypothesis - I
9 don't pretend the possibility of any certainty with
10 any of these things, but as a hypothesis there is
11 something about the pathophysiology of this child
that may explain his death.

12 A. There is?

13 Q. Well, I am asking you, as a
hypothesis.

14 A. I am not sure what you are
15 referring to.

16 Q. Well --

17 A. I hadn't considered that.

18 Q. You hadn't considered that?

19 A. No.

20 Q. Let me deal with one other
possibility.

21 Dr. Costigan was treating this child
22 at Volume 45, page 36 -- through to page 35. I don't
23 want to read it all -- explains that to reduce the
24

25



1

2 FF7 potassium level he took three aggressive courses of
3 action. I don't know if you have read that transcript?

4

5 A. No, I have not seen this
6 testimony. I would like to see it if you are going
7 to refer to it.

8

9 Q. I don't want to take the time
10 to read it all, but he administered atropine. He
11 gave an enema of an exchange resin which exchanges
12 sodium for potassium across the bowel wall and it
13 actually removes potassium from the body.

14

A. That is kaexelate.

15

Q. You are familiar with that?

16

A. Kaexelate, is that what he
17 said?

18

MS. SYMES: Page 66 of the chart.

19

THE WITNESS: I want to see the
20 testimony if we are going to talk about it.

21

MR. SCOTT: Q. He increased the
22 concentration of glucose. It is at page 36, 37, if
23 you have got that, at the bottom.

24

A. I just received it. Thank you.

25

Q. I think if you begin at line
19, doctor. He says:

"Q. How do you treat high potassium?"

A. What we did was, we did a few



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FF8 2 little avenues, a few approaches..."
3 and then read over half-way down page 37.

4 Have you got that?

5 A. I am on page 37. I was reading
6 page 37.

7 Q. Have you got to the three things
8 he said he did?

9 A. He gave the resin.

10 A. He gave the glucose.

11 Q. And he gave the atropine.

12 A. That is actually on page 35.

13 A. 35?

14 Q. Yes, at line 15. Do you see
15 that?

16 A. I see he gave it but I don't
17 see any relationship to reducing potassium.

18 Q. All right. Well, with that
19 rider can I ask you now to turn to page 45.

20 A. In fact, I think he gave it
21 to increase the heart rate.

22 Q. Pardon?

23 A. To increase the heart rate.

24 Q. Can I ask you to turn to page
25 45 where Mr. Lamek asked Dr. Costigan this question:



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FF9

2 "Did it occur to you that by the
3 administration of medications designed
4 to lower the potassium level, the
5 result may in some way have been to
6 aggravate the digoxin toxicity that
7 may have existed?"

8

"A. Yes."

9

Do you see that?

10

A. Yes, I see it.

11

Q. Well, I suggest that to you as
12 a hypothesis that it is at least hypothetically
13 conceivable that the administration of these medica-
14 tions aggravated the digoxin toxicity that existed.
15 That is, made lethal what was there.

16

A. My comment to that would be that
17 it is true that an abnormally low potassium level will
18 predispose an individual to toxicity from a smaller
19 amount of digoxin.

20

I am not sure I would agree that
reducing an abnormally elevated potassium concentration
21 to a normal concentration would increase toxicity.

22

Q. Well, Dr. Costigan was the
cardiologist treating the child.

23

A. Right.

24

Q. I can tell you that. And he

25



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FF10 2 said that it occurred to him that the results of
3 his medications might be to aggravate the digoxin
4 toxicity. So we have his assumption --

5 THE COMMISSIONER: It was a concern
6 of his.

7 THE WITNESS: I agree that it occurred
8 to him.

9 MR. SCOTT: Q. All right.

10 A. I mean I can't comment on that.
11 That is his testimony and I don't --

12 Q. He was the Chief Resident
13 and the cardiologist looking after this baby at the
14 time.

15 Now what I am suggesting to you is
16 that --

17 MR. OLAH: I think in all fairness,
18 Dr. Costigan, I think it was in retrospect also.

19 THE COMMISSIONER: Oh, yes. I
20 don't have any trouble with that. I think the situa-
21 tion was that he was concerned, and I think this was
22 post mortem, that all that he had been doing to try
23 to relieve the potassium count might in fact have
24 resulted in --

25 MR. SCOTT: I agree. I agree.

26 THE COMMISSIONER: -- in something --



Kauffman
C.R.E.X. (Scott)

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FF11 2

MR. SCOTT: I agree.

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Q. What I am saying, bearing in

mind that this child was on digoxin therapy, is it
conceivable that these ministrations, well intentioned
and no doubt quite proper, may have made legitimately
administered digoxin lethal in the case of Baby
Pacsai?

A. I think if they were effective
enough to lower his potassium to very low, abnormally
low concentrations, that is a possibility, yes, I
think it is conceivable under those circumstances.

We don't have any evidence that that
occurred, but if indeed it would have, it could have
increased the susceptibility to digoxin toxic effects.

Q. I take it that it follows on
that hypothesis that the digoxin already present
might have killed the child --

A. Well --

Q. -- without any illicit
administrations?

—



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2 A. Well, I don't know if I would
3 go that far, it depends on how much was there.

4 Q. It depends on a whole lot of
5 assumptions, doesn't it, just like every other theory.

6 A. There are a lot of children
7 with normal amounts of digoxin in their body who have
8 some degree of hypokalemia who do not die from digoxin
9 poisoning. In fact, that is probably the usual rather
than the exception.

10 Q. Well now, one other problem in
11 your evidence before the Murphy inquest, you said at
12 page 13, and let me just read it to you. It is
13 perhaps now conventional wisdom for us in this Inquiry:

14 "A. I have to respond to that by
15 saying that the symptomatic signs of
16 digoxin toxicity in infants are rather
17 non-specific and usually are symptoms
18 that can be due to other factors. And
19 it is difficult in many situations in
20 a clinical situation to be certain
21 whether or not a specific symptom is
22 due to or not due to digoxin in a
23 child and this is where levels come
24 in handy sometimes to help you sort
25 that out. Vomiting, it is true that



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"vomiting, loss of appetite, irritability
can be symptoms associated with toxic
digoxin effects. They can also be
associated with a myriad of other
things in infants this age and that's
why it is so difficult to make a
definite association."

8

Now, I take it you remember giving that
evidence?

10

A. Yes, I do.

11

Q. And you accept it today as
you accepted it then?

13

A. I think I still agree with
myself, yes.

14

Q. Yes. As time passes we may
all change our minds to these complicated questions,
Doctor, but for the moment nothing has changed in
the literature that leads you to qualify that?

18

A. With that piece of my evidence
I think I still agree.

20

Q. Right, yes. I take it that
seizures are not indicators of digoxin toxicity?

21

A. Well, they have been
associated with severe digoxin toxicity, yes.

23

Q. But they are not explicit?

24

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A. They are not proof of digoxin
toxicity, no.

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Q. Now, you see, one of the other
problems we have in this case is, Dr. Fowler, who
is a cardiologist, gave evidence and put forward a
paper that he had prepared - it is Exhibit 174 - in
which he reported dealing with some other babies, a
sample of 31 babies in the Hospital, that seizures
were noted in only 1 out of 31 cases. That was 3
per cent. He also gave evidence here that he had
reviewed the literature and the literature showed
seizures in 1 out of 16 cases, or 6 per cent. I take
it those sorts of figures ---

MR. HUNT: Well, if my friend is about
to ask the witness about that evidence or that paper
then the witness should have that paper.

MR. SCOTT: I am not about to ask him
about that, I am simply reciting that evidence.

MR. HUNT: Well then, the witness --
well, I will wait for my friend to answer the question.

THE COMMISSIONER: Wait until you
hear what the question is.

MR. SCOTT: Q. Well, Dr. Bain told
the Commissioner that 16 of the 36 babies with which
we are here concerned showed seizure activity of



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2 various levels of intensity and one example that he
3 gave was the Miller child at page 42 of the chart, was
4 noted to become very rigid and extended legs and arms.

5 Now, first of all, is the level of
6 seizure activity that Dr. Bain noted, in your opinion,
7 an unusually high level?

8 A. I would need to look at his
9 testimony and see the context in which he made those
10 statements and look at them and then I would try to
11 respond to you.

12 Q. All right. Well, perhaps we
13 can get you a note of the page of his testimony and
14 as you are going to be here tomorrow you can look at
15 it at the end of the day.

16 A. I have no disagreement on the
17 face of it. He said the seizure incidence was what?

18 Q. No, he noted, he did a chart
19 review just like you did.

20 A. Yes.

21 Q. He didn't treat any of these
22 babies but he did a chart review of all 36 and he
23 noted seizure activity with respect to 16, that is,
24 half, almost half.

25 MR. ORTVED: I think it was more than
26 36.

27

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GG.5

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MR. SCOTT: Was it?

3

MR. ORTVED: 44 deaths.

4

MR. SCOTT: Q. I am sorry, 16 of our 36.

5

He looked at more deaths that were outside our 36
and he found one or two seizures in those, but of our
36 he found 16 that exhibited seizures. First of all,
I ask you, is that, according to your understanding
of the literature, a very high proportion, or is it
not or do you have any opinion on that?

10

A. Proportion in infants this age
with severe heart disease?

12

Q. Yes.

13

A. Or proportion of ---

14

Q. You see ---

15

A. You see, I'm not sure what

population you're having me compare them to.

16

Q. We are talking of young

17

cardiac babies. You see, Dr. Fowler's review, it is

18

true you haven't seen it and I can't ask you to

19

comment on it but he gave his review of the literature

20

and produced a figure, don't worry about that.

21

Dr. Bain gave an analysis of the seizures he found in

22

our 36 and what I am really asking you is, have you

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anything to say or is that a matter for cardiologists

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as to whether that is an inordinately high proportion?

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A. Well, if you are talking about a group of small infants who were admitted to a tertiary hospital with severe heart disease, I'm not sure that's a high incidence; if you are comparing them to a general population of infants and children I think it would be a high incidence. I'm not sure what denominator you are asking me to use?

THE COMMISSIONER: Can I try to help out here. I think that the position that is being taken, let me put it this way, by some doctors, if these children all died of digoxin poisoning, would this not be a symptom of digoxin poisoning, not normally be, it is odd that so many of them suffered from seizures. That is what they are saying and have you any comments on that?

THE WITNESS: Well, I'm not sure I can follow that assumption because seizures are due to so many causes in infants this age that they may have had by chance other conditions that caused seizures. I mean, the fact of the incidence of seizures was different from some other sample from another population I don't think really tells me one way or the other whether they may have been related to digoxin.

MR. SCOTT: Q. Well, the first



GG.7

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2 question I should ask is, is this a question for a
3 pharmacologist or is it a question for a cardiologist
4 or a pathologist? Am I asking the right person?

5 A. I think it is an appropriate
6 question for a paediatrician, of which I am one.

7 Q. All right. Well then, you
8 are entitled to answer. The Commissioner has put the
9 problem to you. Is there something else going on
10 here that we don't know about, bearing in mind that
11 seizures not usually indicative of digoxin toxicity
12 occurred in 16 out of 36 cases?

13 A. Well, there were a lot of
14 other things going on with these kids other than
15 digoxin.

16 Q. Well, is there anything going
17 on connected with that that may have led to
18 their deaths?

19 A. I don't know. If I follow you,
20 I don't think I can answer that, I mean, if I under-
21 stand the point of your question, the meaning of your
22 question. I'm not sure I can answer it, I may have
23 to say I don't know. You see, the seizures, we could
24 use another symptom, we could say vomiting or we
25 could say high respiratory rate, or whatever. There
are so many other things that can influence the



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2 incidence of those symptoms other than digoxin and
3 that's why it is difficult to use them as definitive
4 signs of poisoning.

5 So that a change, even if this
6 incidence is high, compared with some other, whatever
7 other comparison population we have, which we haven't
8 defined at this point, whether it is high or lower
9 than some other population, I'm not sure, I don't
10 think it makes any difference to me in terms of
11 trying to say whether or not digoxin was involved
here. It is not terribly helpful to me.

12 Q. You see, Doctor, let me put
13 the problem this way. Lawyers like simplistic
14 solutions and I would like one if I can have one but
15 maybe there can't be one. What you have here is, as
16 you know, a number of babies who died exhibiting
17 symptoms that have been described time and time again.
18 Because there are in the case of a number of babies
19 digoxin in their system which should not be there,
20 there is a tendency to holus bolus say, well then,
21 any babies who were in doubt were killed by digoxin.
22 There is a tendency on the part of the cardiologists
23 to say, well, these babies had grossly diseased hearts
24 and they probably died of - you can't say natural
25 causes but you know what I mean, they are cardiac



GG.9

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2 conditions of which there is said to be some 13
3 possibilities.

4 What I am saying to you is, we know
5 one fact, according to Dr. Bain, that 16 out of 36
6 exhibited seizure. Is there a possibility that there
7 is something else going on here or must we maintain
8 these blinkers with only two options or is it too
early to say?

9 MR. HUNT: Dr. Kauffman has said he
10 would like to see the evidence of Dr. Bain with
11 respect to the seizures before he gets into it.

12 MR. SCOTT: Well, I would like to ask
13 him the general question.

14 THE WITNESS: I think I would be
15 willing to answer this and, that is, I don't think
16 the incidence of seizures in these 36 babies is
17 helpful to me in any way in addressing that question
18 in trying to decide whether or not digoxin played a
19 role in any one of them. I don't see the incidence
20 of seizures in these 36 babies as being helpful to me.

21 MR. SCOTT: Q. Well, no, again, you
22 see, you are saying I don't see the number of seizures
23 as helpful in proving or disproving a digoxin theory.
24 I understand that. What I am saying to you is, is
25 it possible that the incidence of seizure activity



GG.10

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2 points to some other possibility about these babies
3 that we haven't considered?

4 A. That's when I said I don't know.

5 Q. No. Well, what I am trying to
6 get you to help me with is, is it possible that there
7 are other factors that we haven't unearthed? Are we
8 driven to murder on one side and to natural causes on
the other?

9 THE COMMISSIONER: Could we just change
10 that question a little, please?

11 MR. SCOTT: I'm sorry, the word is
12 offensive but that is what we are talking about.

13 THE COMMISSIONER: No, but are we
14 driven to digoxin intoxication on one side or ---

15 MR. SCOTT: Digoxin intoxication on
16 one side or sick babies dying on the other or is there
another possibility?

17 THE WITNESS: Well, I thought the sick
18 babies on the other hand included all the other
19 potential possibilities.

20 MR. SCOTT: Q. Well, they may well.

21 A. I mean, that is kind of a --
22 anything else that may well have contributed to their
23 death.

24 Q. But then I point out to you a

25



GG.11

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2 fact that can be demonstrated, that an uncommonly
3 high number, according to Dr. Fowler and Dr. Bain,
4 exhibit this phenomena. Does that help you at all?
5 If it doesn't, say so.

6

A. No, it does not.

7

Q. All right.

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MR. YOUNG: Excuse me, Mr. Scott, if
you are about to move on to another point perhaps the
record should be clear. You have referred to Dr.
Costigan as the presiding cardiologist with respect to
Baby Pacsai early today.

MR. SCOTT: I'm sorry, he was the
chief resident.

MR. YOUNG: You corrected Dr. Kauffman
when he said someone else in the Cardiology Department.
To be clear, I have examined Dr. Costigan's C.V. and
I see no evidence of him having spent any time in
the Cardiology Department. He is a very well
qualified doctor but not in cardiology.

MR. SCOTT: He is the chief resident,
I am sorry.

MR. HUNT: And if my friend would give
us the reference to Dr. Bain's evidence that he has
referred to we will ask Dr. Kauffman to look at it.

MR. SCOTT: Yes, you will get that



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Kauffman, cr.ex.
(Scott)

6226

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2 a little later towards the end of the day.

3 MR. HUNT: I appreciate that.

4 MR. SCOTT: Q. Well now, let's just
5 carry this business of the seizures one step forward.
6 In the Miller case we know from page 42 of the chart
7 that she became very rigid and extended legs and arms.

8 A. Just a minute, I want to look
9 at the chart with you. I'm sorry, what page?

10 MR. SCOTT: 42.

11 Q. So, the Miller child was in

12 seizure at some point in time.

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Kauffman, cr.ex.
(Scott)

HH
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DM/cr

2

A. I am sorry, were you asking
3 me or ---

4

Q. I am simply noting that she
5 was in seizure at that time, do you agree?

6

A. She was described as, in fact
the word "seizure" is used.

7

8

Q. Then she was in seizure, there is
no doubt about that?

9

A. Yes, I think so.

10

11

Q. And then at page 5690 and
5691 you are asked this question.

12

13

A. Where are you referring to
now?

14

THE COMMISSIONER: Your evidence.

15

16

Q. Your evidence where Miss
Cronk was examining and I am reading beginning at
line 18:

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"At 1:45 we see the irregularity in
the child's apex and the gagging and
the vomiting to which you have referred
but it is almost an hour later - well,
it is indeed an hour later when it is
noted that she began seizure-like
activity. When you talk, Doctor, of
the onset of the critical symptoms,



Kauffman, cr.ex.
(Scott)

1

2 "do you have one of those two specific
3 times in mind?

4 A. Well, I was actually relating
5 the onset to the increasing bradycardia
6 and irregular heart rate and the
7 gagging and vomiting. I think that
8 could have been the onset of the
9 symptoms that have progressed to the
10 other symptoms that followed. There
11 is a complicating factor and, that
12 is, because of her rapidly deteriorating
13 condition the seizures could possibly
14 be related not to digoxin but to lack
15 of oxygen or acidosis or other things
16 that were interfering over that short
17 period of an hour when she was
18 rapidly deteriorating."

19 Now, you recall giving that answer?

20 A. Yes.

21 Q. Now do I take that to mean
22 that the child was rapidly deteriorating?

23 A. To use your phrase.

24 That was my impression from
25 reading the chart during that period of time.

Q. And the seizures were one

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2 result of that?

3 A. They were part of the symptom
4 complex that was described during that period of
5 time.

6 Q. Are you suggesting that that
7 is about the time when the digoxin was administered,
8 the illicit dose?

9 A. No.

10 Q. When was the illicit dose in
11 your opinion?

12 A. I think if it was administered
13 it was, it preceded the onset of these other
14 symptoms that I alluded to in the testimony that
15 you just read me.

16 Q. Well, when? Well you see
17 what I am getting at, if the seizures are not
18 manifestations of digoxin toxicity.

19 A. I didn't say that. She did not
20 have all these symptoms in one moment of time, she
21 had a series of symptoms resulting that you might
22 anticipate if she ---

23 Q. Now I understood you to
24 say ---

25 A. Because of her cardiac
condition deteriorating.



Kauffman, cr.ex.
(Scott)

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2 Q. Now I understood you to say
3 that seizures were not an indication of digoxin
4 toxicity?

5 A. They may or may not be. I
6 didn't say they never were, I said they may or may
7 not be.

8 Q. So they are neutral?

9 A. They may be caused by digoxin;
10 they may be caused by anything.

11 Q. I see.

12 A. In fact in this child this
13 seizure may have been due to the acidosis and the
14 hypoxia which was produced by the arrhythmia due to
15 a toxic dose of digoxin. In that situation you might
16 say that the seizure was not directly related, not
17 directly caused by the digoxin but indirectly the
18 course of events that were set in motion by a
19 digoxin toxic dose that could have resulted in
20 seizures.

21 Q. Well what I am suggesting to
22 you is that the child; that it is consistent with
23 the child's cardiological history to be at this
24 stage in a rapidly deteriorating condition, exhibiting
25 inter alia a seizure, that is consistent with her
cardiological symptoms.



Kauffman, cr.ex.
(Scott)

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2 A. With the acute symptoms at
3 this time?

4 Q. Yes.

5 A. Yes.

6 Q. Isn't that so?

7 A. The seizure is consistent with
her cardiac problem at that point in time, yes.

8 Q. Then I take it that what you
9 are suggesting is that the rapidly deteriorating
10 condition of the baby and the seizure, occurred,
11 would have occurred, or might have occurred whether
12 the digoxin was administered an hour before or not,
is that fair?

13 A. Did I say that?

14 Q. No, but is that fair, I am
15 asking you.

16 A. Well, if there was another
17 cause for her to suddenly change and develop these,
18 this course of symptoms that is a possibility, yes.

19 Q. No, I think you have agreed,
20 Doctor, that her rapidly deteriorating condition
21 and her seizure which led to her death was a result
22 of her - might be a result of her cardiological
condition absent digoxin?

23 A. I agree her seizure very well

24

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Kauffman, cr.ex.
(Scott)

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2 may have been the result of complications of her
3 cardiac arrest and hypoxia and acidosis as a result
4 of poor cardiac output during that period of time.

5 Q. Then why do you necessarily
6 have to insert digoxin in an illicit dose in her
7 case to justify her death?

8 A. Let me go back and go through
9 it again and maybe I can be of some help, if I can
10 find my papers. We are talking about Miller, right?

11 Q. Yes.

12 A. Okay. Her underlying - I have
13 got to refresh my memory on some of the details here
14 so I can answer this for you as completely as
15 possible.

16 Q. You see - I don't want to
17 stop you, but when you say at page 5691:

18 "There is a complicating factor and
19 that is because of her rapidly
20 deteriorating condition the seizures
21 could possibly be related not to
22 digoxin but to lack of oxygen or
23 acidosis or other things that were
24 intervening over that short period of
25 an hour when she was rapidly
deteriorating."



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What I am asking you is, is there a hypothesis upon which her death can be explained without the intervention of an illicit dose of digoxin?

A. I think so. I think that there are several hypotheses and we considered them all.

Q. That is all I want to get out of it. But a digoxin dose is not necessary to explain the circumstances in which this poor baby died.

A. She could have had a sudden death due to her underlying heart disease that could have had symptoms not unlike those which were described.

Q. Now one other thing that causes me trouble is - I understand from the evidence that we would expect to find ethyl alcohol in babies because dig. is about 10 per cent alcohol, is that right?

A. I think the propanolol preparation is about 10 per cent ethyl alcohol in it, yes.

Q. Now at page 1 of Exhibit 95-1, and I don't think it is necessary to go through it unless you want to; Mr. Cimbura notes



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Kauffman, cr.ex.
(Scott)

6234

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8 2|| that methyl alcohol was found in the tissues of
3|| Cook and Pacsai.

4|| A. Where is this?

5|| Q. It is Exhibit 95.

6|| A. In his report?

7|| Q. I think that is his report.

8|| THE COMMISSIONER: It is not page 1,
9|| it must be some other page, is it not, 95A is it?

10|| MR. SCOTT: It is D, I am sorry.

11|| MR. OLAH: Exhibit 95D, Mr.

12|| Commissioner, capital D for Donald.

13|| Q. I can show you this.

14|| A. Yes, it would save me.

15|| Q. It is just a note at the
16|| bottom, do you see it?

17|| A. No.

18|| Q. Now, methyl alcohol is a
19|| poison, isn't it?

20|| A. Yes, it is.

21|| Q. And it is highly poisonous.

22|| How can we account for its presence in the samples
23|| of Cook and I think Pacsai?

24|| A. I really can't be helpful with
25|| that, I don't know, I would have to, you would have
26|| to ask the individual or whoever ran the samples.

27|| I notice that he made a statement that he thought



1

9 2 these were artefacts. I don't have any knowledge
3 with which I can be helpful to you on that.

4 Q. What does an artefact mean to
5 you, what does that word mean, that it is an artefact.

6 A. It is usually something which
7 appears to be present and actually isn't, or it is
8 actually present but it was caused by some manipulation
we did in the process of measuring it.

9 Q. I see. Now I know you were
10 asked about these yesterday and I have to pursue it
11 even at the risk of offending momentarily the
12 Commissioner.

13 I take it in dealing with this
14 difficult problem, Doctor, you were anxious to
15 try and examine these deaths as it were in
isolation one from the other.

16 A. I am not sure what you mean.

17 Q. Let me tell you; one of the
18 problems, I shouldn't say one of the problems, one
19 of the facts of this case is that it is made up of
20 medical testimony and explanations for deaths; and
21 it is also made up of a statistical analysis, the
elevated levels, the elevated levels dropping off,
22 do you follow me?

23 A. Are you talking about Pacsai?

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Q. All 36.

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A. The whole picture?

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Q. Yes, the whole picture is

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part medical analysis; but in the background of the
medical analysis is a profile of deaths in the
Hospital that has been described?

7

A. Yes.

8

Q. And I take it to be self-evident that if the only baby to die in six months
was Pacsai we would not perhaps have a case of the
type we have now, it is the profile that tends to
inform the medical examination. Do you see something
of that in this case?

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A. If I understand your question
correctly I think that, yes, the facts that babies
were dying at a higher rate than they were expected
caused somebody, or somebody in the Hospital to
say, hey, what's going on, let's start looking.

18

19

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Q. So it is the fact that babies
died in the period, does that have any significance
for you in assessing the cause of their death?

21

22

A. Only to the extent that in
determining the babies I was asked to review their
charts.

23

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Q. All right. Now, I am going



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2 to ask you, Gary Murphy died and you have defined
3 the categories 5 through 1. I am going to ask you
4 to assume that Gary Murphy died on March 18th of
5 the epidemic period. I am going to ask you to look
6 at your definition, and I wonder where you would put
7 Gary Murphy and why.

7

8 MS. CRONK: I am trying to remember,
9 sir, whether Mr. Scott or it was Messrs. Scott and
10 Hunt who objected to that question yesterday.

10

11 THE COMMISSIONER: I think you are

12 quite right.

13

14 MR. HUNT: Mr. Scott wasn't here so
15 it was me.

16

17 THE COMMISSIONER: Poor Miss Cronk she
18 tried that question and then withdrew it. I thought
19 it was because it irritated you but it might have been
20 Mr. Roland.

21

22 MS. CRONK: No because the witness
23 said he didn't know where he would place the child.

24

25 THE COMMISSIONER: No, I thought, and
26 maybe that was some other place. Let's try it any-
27 way, we will now get to it, where would you have
28 put Murphy, back in, what if he had died; but I take
29 it your assumption is that he is doing it at the same
30 time as he is doing the other babies?



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MR. SCOTT: Q. Yes. On the assumption you were doing it at the same time as you were making the other analysis, and on the assumption that the baby died within the epidemic period.

MR. HUNT: Mr. Commissioner, I think nothing has changed between yesterday and today inasmuch as the witness was told yesterday that he didn't have to answer a question such as that because it really wasn't going to assist us, but if he wanted to he could. Yesterday he said he didn't know how he would answer it, and today he surely doesn't have to.

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1dec83 2 THE COMMISSIONER: You see there you
II
EMTra 3 are. There is a fellow with a good memory and he
4 has got me down to rights.

5 MS. CRONK: Now that I have woken up.

6 THE COMMISSIONER: I did say yester-
day --

7 MR. SCOTT: Look, we have all changed
8 our minds, including the doctor, about the Baby
9 Estrella so I am sure your lordship --

10 THE COMMISSIONER: They used to say
11 about judges when they do that sort of thing but I
12 think I will still say to him that he needn't answer
13 because the important thing to us is not what he would
14 have done but what he now thinks in the state of his
15 intellect, but I don't think I forbade him from
16 answering that yesterday, and if you want to answer it
17 you are entitled to do it.

18 Yes, Mr. Olah?

19 MR. OLAH: He did in fact answer
20 yesterday.

21 MS. CRONK: He did answer it.

22 THE COMMISSIONER: Well you see maybe
23 today he will be able to do even better.

24 MR. SCOTT: One of the difficulties
25 with this case is our analysis of it is formed by the



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IT2 2 death profile in the Hospital, and that is a fact of
3 life with which we must come to terms. But everybody
4 who has examined this case from the Chief Cardiologist
5 down has said if Cook is -- if Cook gets an illicit
6 overdose of digoxin then maybe eight or ten or twelve
7 of the babies before Cook -- if there is a person
8 in the Hospital who would do that then maybe other
babies are high risk babies.

9 Now I just want to put Murphy into
10 that context.

11 Q. If Murphy had died before
12 Cook where would we have put Cook on our ratings list?
13 Are you able to help us, doctor?

14 A. If Murphy would have died
before Cook?

15 THE COMMISSIONER: Well let's say
16 a couple of days before.

17 MR. SCOTT: Q. If Murphy had died
18 the same day as Miller, Baby Miller, when you were
19 asked to examine ten, you would have been asked to
20 examine eleven including Baby Murphy.

21 Are you with me so far?

22 A. You are talking about before
Cook?

23 Q. I, , .

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A. I thought you said if Murphy
3 died --

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Q. If the Crown Attorney asked you
to examine ten babies, one of them was Cook, and nine
were babies who had died before Cook in terms of time,
and he asked you --

THE COMMISSIONER: Oh, just a moment.

MS. CRONK: Sir, this is just not
right. He was asked to review all the
cases of the period --

MR. SCOTT: It doesn't make any
difference.

MS. CRONK: Well, put it correctly,
Mr. Scott, or I wouldn't be on my feet.

MR. SCOTT: All right.

Q. Will you tell us again - Miss
Cronk wants to hear it - will you tell us again
precisely what you were asked to do.

A. By?

Q. By the Crown Attorney.

A. The Crown Attorney asked me
to review some 30 odd cases to assist them in whether
or not --

Q. You were to provide an
opinion?



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2 II4 A. I was to provide an opinion as
3 to whether or not digoxin might have played a role
4 in the deaths of any of those babies.

5 Q. Yes.

6 A. From a pharmacologic point of
7 view.

8 Q. All right. And what did CDC
9 ask you to do?

10 A. They asked me to look at 37
11 cases.

12 Q. Yes.

13 A. And they asked me to put a
14 numerical rating of probability on those cases as to
15 the probability that their deaths might have been
16 related to digoxin.

17 Q. All right. And the 36 cases
18 that were referred to you by the Crown Attorney or the
19 37 referred to you by the CDC all ended chronological-
20 ly with the death of Baby Cook..

21 Baby Cook was the last of the
22 sequence to die.

23 A. I don't remember. If that is
24 factual, I will accept that.

25 Q. All right. Now what I am asking
26 is that if the Crown Attorney and CDC had added the

27

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Kauffman
cr.ex. (Scott)

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115 2 name to your list of a baby who died before Cook died,
3 who exhibited all the characteristics of the death
4 of Baby Murphy, how would you have ranked that death?

5 Are you with me?

6 A. I think so.

7 MR. HUNT: That is only if the
witness wants to answer.

8 MR. SCOTT: Sure. I am not going to
9 extract an answer that he doesn't want to give. He
10 is a professional. If he doesn't want to give it, he
11 won't.

12 MR. OLAU: He answered yesterday,
13 Mr. Commissioner. The answer is at 5827.

14 THE COMMISSIONER: Do you want to
see what you said yesterday?

15 THE WITNESS: I was just going to
16 say --

17 MR. SCOTT: Q. Well, if you have
18 answered it, I don't want to ask you to answer it
19 again.

20 A. I will give the same answer
21 that I gave yesterday, and very honestly, considering
22 all that has happened in the intervening time I don't
23 know how I would have ranked it at that point in time.

24 Q. Is that the answer?

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116 2 MR. OLAH: That is the answer.

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4 MR. SCOTT: Q. Let me put this to
you, doctor: I want you to take overnight and I want
5 you to answer that question if you can.

6

7 When you were given this task by
CDC, you were given the charts or some other material.
8 You were allowed to select your own ranking system,
which I think you did.

9

A. Yes, that is correct. I --

10

Q. Then --

11

A. I didn't design the form but I
did define the criteria.

12

Q. And then you after looking at
the charts for whatever length of time you felt
14 was desirable or necessary, you graded the babies and
15 I take it that there is nothing perfect about that
16 grading. It was a human exercise in which you applied
17 your best talent to doing it?

18

A. That is correct.

19

Q. And why can't you do the same
20 for the Murphy record?

21

A. I can do it today. I can't
22 assure you that what I would do today or tonight
23 will be the same as what I would have done a year
ago because of all that has happened in this whole

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117 2 situation since then.

3 THE COMMISSIONER: Wait a minute,
4 doctor.

5 Yes, Ms. Jackman?

6 MS. JACKMAN: Mr. Commissioner,
7 perhaps Mr. Scott could be a bit clearer about what
8 he is asking. I understood the question put to the
9 doctor yesterday was with respect to his rating on
10 the police report and not the Centers for Disease
Control. He does have a ranking --

11 THE COMMISSIONER: No, I thought it
12 was --

13 MS. JACKMAN: -- a ranking system
14 with respect to the CDC.

15 THE COMMISSIONER: I thought it was
16 with respect to the -- I don't think the question has
17 been put --

18 MR. SCOTT: And it is not going to
19 be. That isn't what I would like him to do.

20 THE COMMISSIONER: You would like him
21 to what?

22 MR. SCOTT: I would like him to do
23 what he and I understand.

24 Q. I take it, doctor, you are
25 saying that you don't think you can do that?



Kauffman
cr.ex. (Scott)

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118 2 A. I can sit down and I can go
3 through the Murphy chart with all my other information
4 just as I did a year ago.

5 Q. Yes.

6 A. And I can put a rating on it.

7 THE COMMISSIONER: No, be careful.

8 It was last April, wasn't it?

9 THE WITNESS: No, it was in November
10 of 1982 that I did the CDC ratings.

11 THE COMMISSIONER: Yes, yes. But
12 the Murphy child wasn't until later.

13 THE WITNESS: Yes, that is correct.

14 THE COMMISSIONER: You mean just the
15 way you did --

16 THE WITNESS: Just the way I did
17 with the others.

18 I can do that tonight. All I said
19 was I can't assure you that that will reflect what
20 I would have done a year ago had he been a part of that
21 original set of cases, as you suggest.

22 MR. SCOTT: Q. Are you telling me
23 that if you had done this as part of the original
24 set of cases you might have given Murphy a rating
25 which is different than the rating you would give him
if you sat down and did it tonight?



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A. No, that isn't what I said.

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Q. Oh, what did you say?

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A. I said I can do it tonight but
I can't assure you that I will behave in the same way
as I would have a year ago knowing what I knew then
and knowing and having been through what I have been
through now.

8

Q. Let me ask you this, doctor.

9

If you sat down tonight to apply your ratings to
Cook, Lombardo, Pacsai, Inwood, Miller, Belanger,
Hines, Gage, Estrella and Gonas, would you come up
with anything different than you came up with a year
ago?

13

A. No. I haven't sat down -- I
haven't gone through that exercise.

15

Q. No, but you can do that too.

16

MR. HUNT: Well, Mr. Scott is being
very free with the witness' time.

18

MR. SCOTT: Well, I'm sorry about

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that.

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MR. HUNT: You may be sorry, but just
so that the witness realizes that Mr. Scott can ask
for these things - he may even put it in a sort of
demanding way, but the witness is under no obligation
to spend any time this evening pursuing these

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110 2 exercises for Mr. Scott's purposes if he doesn't
3 choose to or if he doesn't feel they are helpful.

4 THE COMMISSIONER: Well one of the
5 troubles with those exercises -- what all of our
6 examination and cross-examination has been directed
7 to I think is really what is his view now and the
8 purposes of all of these other things, the Atlanta
9 Report and the report to the Crown Attorney are really
only for purposes of cross-examination.

10 What we really want from you, and
11 I think you understand this, I hope you understand
12 it, we want your present opinion, and you may refer
13 to your previous one and counsel will certainly refer
14 to your previous one if your present opinion is
15 different from what it was then, but we really want
16 to ask you your present opinion, and that is why
17 really, basically that is why I told him he didn't
have to answer it.

18 I think Mr. Hunt is right. He didn't
19 have to go through that sort of exercise to say what
20 he would have done with those --

21 MR. SCOTT: No, Mr. Commissioner. The
point I am directing --

22 THE COMMISSIONER: You are asking --

23 MR. SCOTT: -- is different. The

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2 Atlanta Report is not simply an aid to cross-
3 examination. The Atlanta Report when it is released
4 is going to be a major factor in this Inquiry and we
5 are entitled to know how it is made up.

6 Now one of the things that was done
7 by a whole lot of doctors, including this one, was
8 to scale the deaths in a fashion like this, and they
9 did it against a given background, the epidemic
period.

10 THE COMMISSIONER: That is right.

11 MR. SCOTT: Now if there was no
12 epidemic period and they were just scaling the
13 deaths, I have no problem.

14 I want to know to what extent if
15 any the fact that a baby died in the epidemic period
16 may have been significant in the rating it got, and
17 that is an important question, and that is why I say
18 to the doctor that if there are changes in the ratings
I would like to know about them.

19 MR. YOUNG: Mr. Commissioner, I
20 thought the witness answered--

21 MR. SCOTT: It seems to be a thing
22 that is unpopularly received by my colleagues and I
won't press it.

23 MR. YOUNG: It is not unpopular, it

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1112 2 is just that I am not sure how useful it would be.

3 I thought the witness was asked what effect the
4 very fact that these children died within that
5 period had upon him, and I think the only answer he
6 gave - correct me if I am wrong - was that that was
7 the determining factor as to which charts he would
examine, and that was it.

8 Mr. Commissioner, I don't think it
9 serves any purpose for the witness to conduct this
10 entire exercise again this evening, tomorrow evening,
11 this weekend or whenever. If Mr. Scott has a new
12 fact to put to him, I invite him to do so.

13 MR. SCOTT: Well, I am not going
14 to pursue it. I am not going to compel anybody even if
15 I had the power to ask any questions. I simply put
16 this proposition that there can be no doubt in my
17 mind - I may be wrong - that if Baby Murphy had
18 died on March 18th, Baby Murphy would be subject to
19 examination here and would be getting the same kind
of treatment.

20 Baby Murphy died outside the epidemic
21 period and the Attorney General and my friends don't
want to look into the case.

22 MS. CRONK: Well, it is late and --

23 MR. SCOTT: Because it doesn't fit

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III 2 the pattern.

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MS. CRONK: It has been a very long
4 week. If we are now starting legal argument --

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MR. SCOTT: No, no, no. I won't
6 press it.

7

THE COMMISSIONER: If it is any
8 help, Mr. Scott, I don't see any way that I can fail
9 to look into the case because obviously the circum-
10 stances of digoxin levels of Murphy were very similar
11 to digoxin levels of Pacsai, so if I am to make
12 contrary findings on the two of them I obviously
13 have to compare them.

14

MR. SCOTT: Well then is my
15 question useful? I don't want to ask the doctor to do
16 something he is unhappy to do. I don't want to
17 interfere with his spare time.

18

THE COMMISSIONER: What would be most
19 useful and has been asked I think something like
20 twelve times - not by you but other people - to
21 Dr. Kauffman is how if you say that Pacsai died of
22 digoxin toxicity, how could you give all this evidence
23 to the Coroner to the effect that Murphy died a
24 natural death. That's the question and that is the
25 one he has addressed himself to and that is the answer
he has given.



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III14 Now as far as the other is con-
cerned, I am going to -- you are always accusing me
of not making a ruling --

5 MR. SCOTT: Now I am going to get
one, am I?

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THE COMMISSIONER: You are going to
get one. I am not going to require him to do this
tonight. For all I know he may have a date at the
theatre.

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11 MR. SCOTT: I hope he has met some
nice people in Toronto.

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THE COMMISSIONER: If he wants to
do it, if he wants to give some thought to that and
wants to answer it, he may, but there is certainly
no requirement that you are to do that.

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What I want from you is if you have
changed your views with respect to any of these,
and I think you have already answered that, but if
you have changed your view with respect to anything
that you did in the past, please let us know.

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THE WITNESS: I think my testimony
has reflected that there has been no substantive
change in my view of the cases during the past year.

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THE COMMISSIONER: You have heard
Mr. Scott; he wants to know what you would have done



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1115 2 with Murphy or what you would do with Murphy now or
what you would have done then. If you want to answer
those questions --

5 THE WITNESS: I can't answer that
6 now. I would need to sit down and go through the
7 same process again to answer that question.

8 THE COMMISSIONER: You are not
9 required to do it.

10 How much longer do you think you
11 will be?

12 MR. SCOTT: Those are all the
13 questions I have, Mr. Commissioner.

14 THE COMMISSIONER: All right.

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J-1

1 MR. HUNT: Just for the record: that my
2 silence is not taken as agreement with my friend's
3 comments about the Attorney-General not wishing the
4 matter of Gary Murphy to be looked into and I just
5 failed to respond to it.

6 THE COMMISSIONER: His name seems
7 to be bandied about at this Hearing. It is not the
8 first time I have heard Gary Murphy's name.

9 Yes, Mr. Olah?

10 MR. OLAH: Mr. Commissioner, I
11 was assisted by my friends who were going to allow me
12 to go out of rotation and proceed next. Unfortunately
13 I am not available tomorrow morning, so, may I
14 resume my normal rotation and expect to cross-
15 examine tomorrow afternoon?

16 THE COMMISSIONER: Yes. I wish I
17 could promise that that will be what will happen.
18 You may not be reached at all.

19 MR. OLAH: It is obvious the
20 Doctor is going to have to either remain late tomorrow
21 afternoon or come back.

22 THE COMMISSIONER: We will take a
23 poll - another one for what use it is. Mr. Ortved?

24 MR. ORTVED: A half an hour, Mr.
25 Commissioner.

26 THE COMMISSIONER: A half an hour.

27 MS. SYMES: An hour and a half,



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J-2 2 Mr. Commissioner.

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4 THE COMMISSIONER: Well, there is
5 two hours gone and in the ordinary course that is the
morning.

6

How long will you be Miss Jackman?

7

MS. JACKMAN: Possibly an hour.

8

9 Mr. Commissioner, I would like to say I also have the
same problem with tomorrow morning, I don't think I
can be here until 10:30, 11.

10

11 THE COMMISSIONER: Well, you won't
12 be reached before 10:30 or 11, so, you needn't worry
13 about that. I shouldn't make those promises, who
14 knows, lightning might strike both Mr. Ortved and
15 Miss Symes; not that I would wish them any bad luck
but it would certainly enable us to get through it
faster.

16

17 MR. OLARI: We have always got Mr.
Labow and all the other parents' counsel.

18

19 THE COMMISSIONER: Have you any
thoughts, Mr. Labow, how long you will be?

20

21 MR. LABOW: I expect to be about
a half an hour, Mr. Commissioner, and Mr. Shinehoff
22 expects to be between a half an hour and an hour.

23

24 MR. TOBIAS: You are looking at
25 me, Mr. Commissioner and I would think about 15 minutes.



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2 J-3 THE COMMISSIONER: Well, I don't
3 know. I just really want assistance. Is it really
4 worthwhile trying to come early tomorrow morning?
5 Well, I can cut her off, she is on the payroll.

6 MR. ORTVED: Well, it hasn't proved
7 too helpful.

8 THE COMMISSIONER: Well, I can get
9 up and leave.

10 MR. HUNT: You have me again as
11 well, Mr. Commissioner.

12 THE COMMISSIONER: Yes, I know
13 but we didn't have you the first time, so, you
14 didn't take too much time.

15 MR. HUNT: Well, the Doctor
16 hasn't been confused on any issue but I have been
17 confused on a couple of them.

18 THE COMMISSIONER: I see. Well,
19 let's try it at 9:30 because it certainly won't hurt
20 to get through as much as we can. I take it, Mr.
21 Ortved, are you available at 9:30?

22 MR. ORTVED: Yes I am Sir. I
23 should just say that they are threatening to call me
24 down in the Supreme Court and if in fact that happens
25 I may not get up here until later in the day but I
am confident I can be here tomorrow and if I'm not
here then maybe Miss Symes can take over.



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J-4

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THE COMMISSIONER: Miss Symes, will
you be here at 9:30 in case?

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MS. SYMES: I will be here at
9:30.

6

7

THE COMMISSIONER: Yes. All right.
Well then we will have ---

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9

MR. TOBIAS: I hate to make this
a meeting of musical chairs, Mr. Commissioner, but I
have a problem tomorrow morning too as well as
Mr. Olah, Miss Jackman and Mr. Ortved but I can't be
here until ---

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MS. SYMES: I can give you an
undertaking I will go so long.

THE COMMISSIONER: No, no. That is

the sort of undertaking I don't want from you.
Mr. Labow, are you going to be here tomorrow morning?

MR. LABOW: I will definitely be
here tomorrow morning.

THE COMMISSIONER: All right.

Well then we have got two designated hitters ready
to go and that will solve that problem. We will
start at 9:30 tomorrow morning then.

--- whereupon the hearing adjourned at 5:05pm
to be reconvened at 9:30 on Friday, December
2nd, 1983.

